

Before the Committee on Appropriations

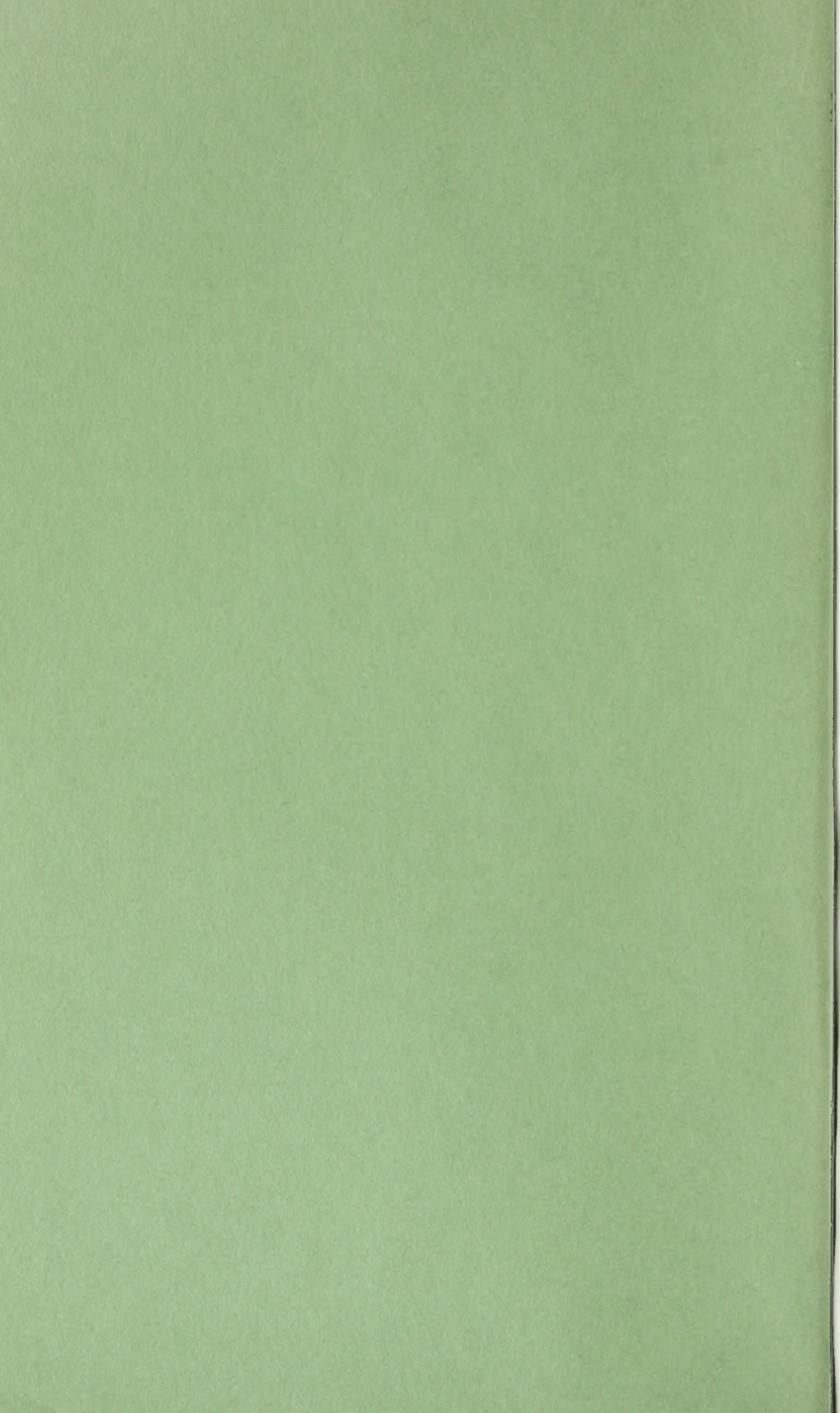
PT. 2

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations

103^d CONGRESS, SECOND SESSION

DEPARTMENT OF LABOR

FEB 8 1995



**DEPARTMENTS OF LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED
AGENCIES APPROPRIATIONS FOR FISCAL YEAR
1995**

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

H.R. 4606

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR,
HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED
AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1995, AND
FOR OTHER PURPOSES

Part 2 (Pages 1-820)

Department of Education

Department of Health and Human Services

Department of Labor

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1995

WEDNESDAY, MARCH 16, 1994

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, Kohl, Specter, Hatfield, Stevens, Cochran, Gorton, Mack, and Bond.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. DONNA SHALALA, SECRETARY

OPENING REMARKS OF SENATOR TOM HARKIN

Senator HARKIN. Good morning. The subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

I might just note before we even start that I am informed that starting at 10 a.m., we have three votes, so I will cut my statement short and perhaps we can get through with Madam Secretary before that 10 a.m., vote.

Today is the first of three hearings with Cabinet secretaries within the jurisdiction of this subcommittee. It is a pleasure to welcome Health and Human Services Secretary Donna Shalala today. She has long been an advocate of children's and early intervention programs, areas where we share a strong mutual interest.

Following Secretary Shalala's testimony this morning we will be hearing from a second panel from the Department, Dr. Phil Lee, Assistant Secretary of the Public Health Service, Dr. Sumaya, Administrator of HRSA, and Dr. David Satcher, Centers for Disease Control and Prevention.

Secretary Shalala has presented an ambitious budget for next year. HHS's total budget request for fiscal 1995 is \$211 billion. In discretionary spending, this budget calls for \$32.9 billion, a \$1.5 billion or a 4.7-percent increase over last year.

Highlighting this budget is \$21.3 billion in investment spending for a variety of President Clinton's children and health initiatives,

\$700 million for Head Start increase, \$310 million more for alcohol and drug treatment, \$93 million more for Ryan White, and \$424 in mandatory spending for immunization. This year's addition to the investment initiatives is the National Institutes of Health with a \$517 million increase over the 1994 appropriated level.

PREPARED STATEMENT

I will dispense with the rest of my statement and ask that it be put in the record.

[The statement follows:]

STATEMENT OF SENATOR TOM HARKIN

Good morning, the Subcommittee on Labor, Health and Human Services, Education and Related Agencies will come to order.

Today is the first of three hearings with Cabinet secretaries within the jurisdiction of this subcommittee to discuss the fiscal year 1995 budget.

It's a pleasure to welcome Health and Human Services Secretary Donna Shalala to the Subcommittee today. Secretary Shalala has long been an advocate of children's and early intervention programs—areas where we share a strong mutual interest.

Following Secretary Shalala's testimony this morning, we'll be hearing from a second panel of witnesses from the Department. Testifying will be: Dr. Philip Lee, Assistant Secretary, Public Health Service; Dr. Ciro Sumaya, Administrator, Health Resources and Services Administration; Dr. David Satcher, Centers for Disease Control and Prevention; Dr. Elaine Johnson, Acting Administrator, Substance Abuse and Mental Health Services Administration; and Bruce Vladeck, Administrator, Health Care Financing Administration.

Secretary Shalala has presented an ambitious budget for next year. HHS's total budget request for fiscal year 1995 is \$211 billion. For discretionary spending, this budget calls for \$32.9 billion, a \$1.5 billion or 4.7 percent increase over last year.

Highlighting this budget is \$21.3 billion in investment spending for a variety of President Clinton's children and health initiatives. Heading up this package is a \$700 million increase for Head Start, \$310 million more for alcohol and drug treatment, \$93 million more for Ryan White, and \$424 million in mandatory spending for immunization. This year's addition to the investment initiatives is the National Institutes of Health, with a \$517 million increase over its 1994 appropriated level.

OUTLAY CRISIS

Before you begin testifying Madame Secretary, let me briefly discuss the budgetary pressures facing our subcommittee for the coming year. President Clinton, in his State of the Union Address, said that this will be "one of the toughest budgets ever presented to Congress." The reason is simple. To paraphrase political consultant James Carville, "it's the budget caps, stupid."

The first chart highlights the source of this pressure. Last year's Reconciliation bill essentially froze discretionary outlays for five years. Under these tight caps, discretionary spending for fiscal year 1998 will be the same as fiscal year 1993 levels, and \$62 billion below CBO baseline.

Our subcommittee is not immune from these pressures, and the main source of the problems are the President's investment initiatives. This subcommittee includes nearly all of the President's "putting people first" programs, and 40 percent of the President's entire investment package, far greater than any of the twelve other appropriations subcommittees. Nearly all the increases the administration proposes for this subcommittee are devoted to the President's investment initiatives.

The next chart proves this point. Of the \$4.7 billion increase in budget authority for this subcommittee, \$4.23 billion is devoted to investments. For outlays, investment increases total \$2.6 billion, \$2 billion more than the \$600 million net increase for the entire subcommittee. Again, using OMB's numbers, that means even if we get an allocation that matches the President's budget request for our subcommittee, outlays for our bill's non-investment programs will have to be cut by \$2 billion. That's an outlay crisis!

Our budget's biggest problems, Secretary Shalala, are created by your department. The reason is obvious—to paraphrase Willie Sutton, HHS is where the outlays are! First, your budget proposes freezing approximately 80 individual programs, many of which are very popular with members of this subcommittee, including Com-

munity Health Centers, Breast and Cervical Cancer Screening, Lead Poisoning Prevention, and the National Health Service Corps.

In addition, the HHS budget cuts the Low-Income Home Energy Assistance Programs by \$707 million, or nearly 50 percent, below the fiscal year 1994 level. Restoring this massive cut in LIHEAP will require approximately \$650 million in outlays. Further squeezing outlays is an administration proposal to delay approximately \$300 million in obligations in NIH, Head Start, and Child Care. The President's budget also proposes a pause in indirect cost payments to universities and other research institutions at fiscal year 1994 levels, accounting for savings in outlays of between \$60 and \$80 million.

Combined, HHS's proposals alone create a \$1 billion outlay problem. That creates an immense crisis for this subcommittee as we prepare our budget for next year.

Again, I'm concerned that the budget squeeze will strangle a number of our subcommittee's programs which may not be investments for the President but which are very important to many members of Congress and their constituents.

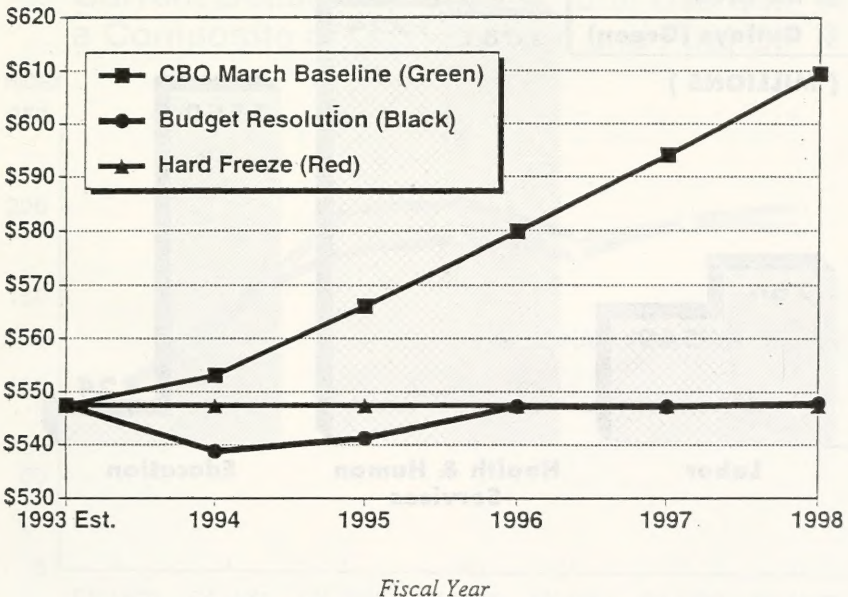
As a first step, we will need your assistance in ensuring for our subcommittee the highest allocation possible, so that we can preserve the President's investment initiatives while working to protect the interests of members of the Senate.

Secretary Shalala, again I want to welcome you to the Subcommittee. I'm looking forward to hearing from you today, and to working closely with you throughout the appropriations process.

At this time I want to yield to Senator Specter for any opening comments that he would like to make.

Discretionary Outlays

(Dollars in Billions)

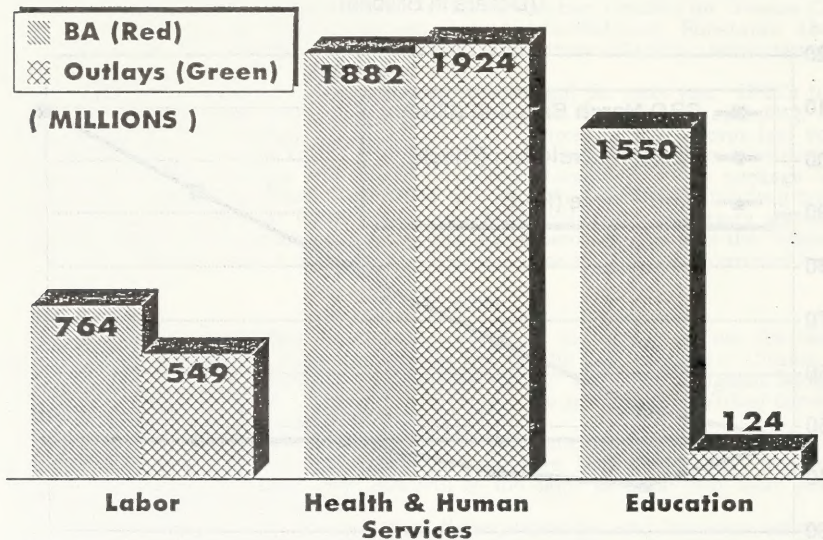


DISCRETIONARY OUTLAYS

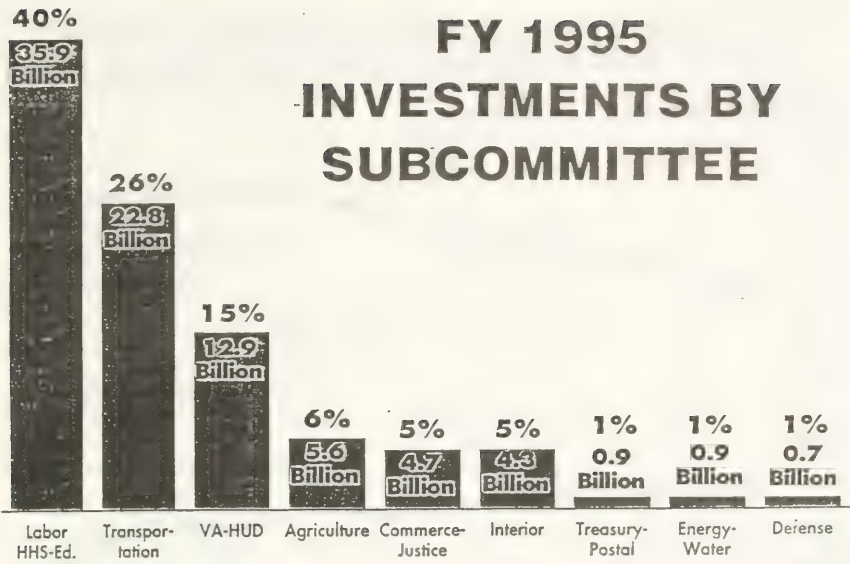
(billions of dollars)

	1993 est.	1994	1995	1996	1997	1998	1994-98
CBO March baseline.....	547.5	553.1	566.1	579.9	594.1	609.5	
Budget resolution.....	547.5	538.8	541.3	547.3	547.3	547.9	
Hard Freeze.....	547.5	547.5	547.5	547.5	547.5	547.5	
Budget resolution compared to:							
CBO March baseline..		-14.4	-24.9	-32.7	-46.7	-61.6	-180.3
Hard Freeze.....		-8.7	-6.2	-0.2	-0.1	+0.4	-14.9

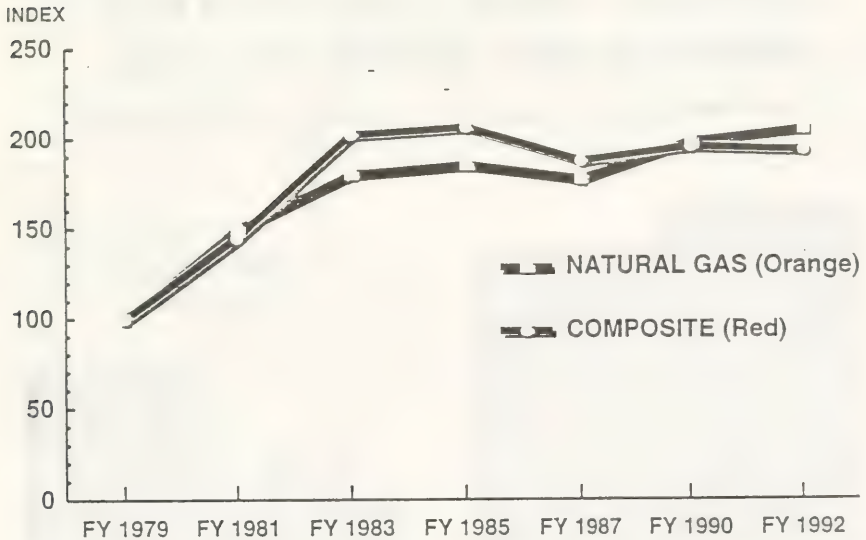
LABOR - HHS - EDUCATION INVESTMENT INCREASES OVER FY 1994



FY 1995 INVESTMENTS BY SUBCOMMITTEE

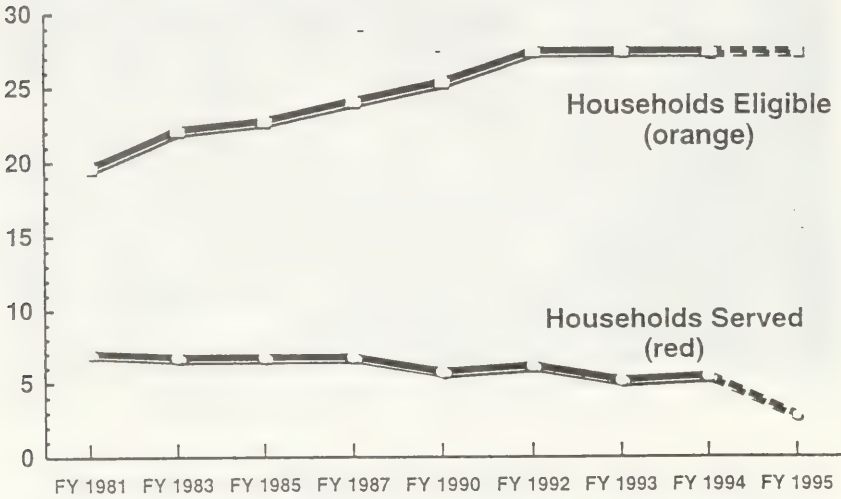


Current Dollar Prices for Natural Gas and a Composite of Gas, Electric and Fuel Oil



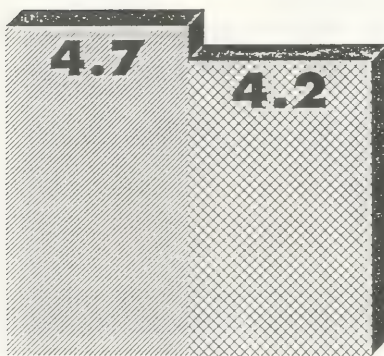
Low Income Home Energy Assistance (LIHEAP) Eligible Households versus Households Served

Households in Millions



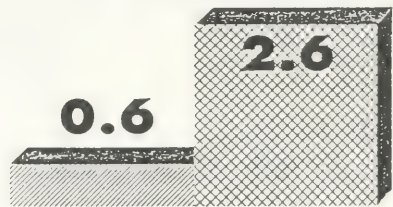
LABOR - HHS - EDUCATION INCREASES OVER FY 1994

Total Increases versus Investment Increases
(Discretionary BA and Outlays)



BA

■ TOTAL (RED)
■ INVESTMENT (GREEN)
(BILLIONS)



OUTLAYS

Source: Office of Management and Budget (OMB)

FISCAL YEAR 1995 HEALTH AND HUMAN SERVICES INVESTMENTS

[In millions of dollars]

	Fiscal year 1995 estimates		Fiscal year 1995 vs. fiscal year 1994	
	Budget authority	Outlays	Budget authority	Outlays
Head Start	4,026	3,529	+ 700	+ 463
National Institutes of Health	11,473	11,009	+ 517	+ 758
Ryan White AIDS	672	627	+ 93	+ 117
Immunizations:				
Discretionary	464	477	- 64	+ 31
Mandatory (vaccine purchase)	(424)	(424)	(+ 424)	(+ 424)
High performance computing	82	79	+ 24	+ 26
Drug treatment	1,040	862	+ 285	+ 158
Social Security disability processing and automation investments	3,098	5,662	+ 608	+ 371
Obligation limitations	2,727		- 281	
Total, Health and Human Services ..	23,582	22,245	+ 1,882	+ 1,924

Senator HARKIN. I want to point to the charts to give us a visual representation of the problems we have. On my far right are the problems we are facing with our discretionary outlays, the green line representing the baseline. We are down on the black line, even below a hard freeze right now. Looking out to 1998, we will not get above that. Next to that are the investments by subcommittee. Fully 40 percent of the President's investment program falls within the jurisdiction of this subcommittee.

On the other side, though, you can see some of the problems we have. Starting here on my left are the three areas Labor, Health and Human Services, and Education investment increases over fiscal 1994. So you can see we have some substantial increases, especially in Health and Human Services, of \$1.8 billion in outlay and \$1.9—I am sorry, \$1.8 billion in authority and \$1.9 billion in outlays.

The far right chart, however, gives us the real problem. The increases in budget authority, \$4.7 billion; outlay, \$4.2 billion; and in the outlay side on the total investment, \$2.6 billion and \$600 million in the outlays, which means, as a matter of fact, that we had about \$2 billion that we had to go someplace else within our purview to find it. And I just might say at the outset that about \$707 million came out of LIHEAP. And again, we find ourselves in a very uncomfortable position.

We want to support the President's initiatives on investment. That is where we ought to be going. But why do we have to take it out of the poorest of the poor, people who make less than \$8,000 who came through a very hard winter, when they need help with their heating and energy bills? And we take about \$600 million out of that account. But that is really what that last chart shows us.

We are taking it out of some of the programs where the need is very great, and we want to explore that with you, Madam Secretary.

With that, I would yield to the distinguished Senator from Oregon, my good friend Senator Hatfield, who is also the ranking Republican on the full Appropriations Committee.

OPENING REMARKS OF SENATOR MARK O. HATFIELD

Senator HATFIELD. Thank you, Mr. Chairman. I would like to welcome the Secretary here this morning, too.

Madam Secretary, I am going to just summarize my opening comments, as well, in an effort to conserve time, and also indicate that in those summary remarks will incorporate some questions that I will submit to you for the record. These are pretty much on the basis of our conversation last week, and I would like to just reiterate them at this time.

My concern about the AHEC program, which you plan to consolidate into a primary program within the Department. I am troubled by the plan to do this. That still has to be authorized as against the budgeting of that. At the moment, the other issue is in the Indian Health Service, where even though you had a 4.5-percent increase or a 4.7-percent increase in the total HHS budget there is a reduction of some 13 percent in the Indian Health Program.

What is even more dramatic is that the reduction of FTE's in the Indian Health Service represents about 83 percent of your total departmental FTE reductions of some 460 FTE's in the Indian Health Service.

The third and last is just another platform. Senator Harkin and I seize any platform that comes along to reiterate our commitment to the proposition that the ultimate cost containment in any comprehensive health program is in medical research. And Senator Harkin and I have introduced legislation calling for such a trust to be set up to supplement—not to replace, but to supplement—the current budgetary process of medical research.

Those are sort of the highlights of the comments I wanted to place on the record today, and as I say, I will follow that up with questions to you for the record.

Thank you very much for being here.

Senator HARKIN. Thank you very much, Senator Hatfield. I would just again repeat for members who just came in that we have three votes starting at 10 a.m., and I would like to get the Secretary's testimony perhaps so she would not have to wait for another 45 minutes before we come back.

Senator BUMPERS.

OPENING REMARKS OF SENATOR DALE BUMPERS

Senator BUMPERS. Thank you, Mr. Chairman and welcome, Madam Secretary. First, I want to apologize to you because when I visited with you yesterday afternoon I did not realize I had to chair an Agriculture Subcommittee hearing on appropriations this morning, and so after the vote I will not be able to return and I apologize for that, and to also say that the chairman and Senator Hatfield have essentially voiced my concerns about this.

As you know, I am greatly concerned about the 50-percent cut in vaccine purchases for Public Health. Obviously, this committee will tinker with that considerably.

The second thing, of course, is LIHEAP. While my section of the country is considered warm and, therefore, does not get the kind of benefits from that program that colder regions of the country

get, I still think it is a very good program and am reluctant to see it cut.

And finally, Arkansas used to have a young, dynamic, handsome Governor who started the AHEC Program in Arkansas, and so I have a paternalistic interest in making sure that it does not get slighted in this consolidation that you are proposing. That will have to happen during the reauthorization process, I suppose, and while this committee has nothing to do with that I will be actively involved in that because the AHEC Program has been just a dynamite program in our State.

Having said all of that, I think your targets and the kind of money you are spending on those targets on people is essentially correct and I applaud you for it.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bumpers. And the ranking member of the Appropriations Subcommittee, Senator Specter.

OPENING REMARKS OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you very much, Mr. Chairman.

I join my colleagues in welcoming you here. I compliment you, too, on your very devoted attention to these very important subjects. You and I have conferred on a number of occasions in advance of this hearing, and I want to express publicly my appreciation for that consideration.

The budget for this subcommittee is extraordinarily difficult and there are many items which raise my concern. And I would second the LIHEAP item as one at the very top of the list. If it is cold in Arkansas, and there may be good reasons for it to be cold in Arkansas, the situation in Pennsylvania is substantially worse and we are going to have to take a very close look at that, as on so many of the items.

I have a long, and I know others here have, a long string of constituents who come to talk to us about so many, many items. What I am recommending to my constituents is that they write to Senator Hatfield. [Laughter.]

And Senator Byrd, and try to find people to write to Senator Byrd and Senator Hatfield, postmarking their letters West Virginia and Oregon. To try to find some greater allocation for this particular subcommittee with Labor, Health and Human Services, and Education, it is very, very difficult. But I know the chairman and I and all the members of the committee will work with you closely in trying to achieve the best balance.

Thank you very much.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

I would just go down the dais here. Senator Bond.

OPENING REMARKS OF SENATOR CHRISTOPHER S. BOND

Senator BOND. Thank you very much, Mr. Chairman. And Madam Secretary, I am delighted to welcome you. I, too, at 10 a.m., am going to have to go to a committee on which I serve as ranking member, the IRS. If we do not get the money in on that side we cannot spend it over here. So I hope that Senator Specter will for-

give us if we try to make sure that there is enough money funded for collections. But I will have a number of questions for the record, and I look forward to reading your testimony.

I am concerned about community health centers and access to primary care. We talked a lot about the needs in health care reform. I strongly support the need to get everybody covered, the need to reform the insurance market, malpractice, administrative reform. But even with that, I think that we have to continue to focus on how we get the health care to people who are arguably covered now who are in a Medicaid program but do not really have access to care, whether it is in an inner city or in a rural area.

We are going to be having a conference in Columbia, MO, at the university with university medical school and the top professionals in our State focusing on how we get access to health care for children throughout Missouri. That, I think, is still a major problem.

IMMUNIZATIONS

We strongly support the need for getting people immunized. I see that the request for vaccines would be more than enough to immunize all the children in the United States. The problem, as a number of doctors practicing with low-income patients tell me, is not that these children do not have immunizations, it is that these children do not have a medical home. The medical homeless, they do not have access to regular preventive health care, of which immunization is an important part but not the only part. And I would raise the question with you whether we need to be spending some of that money on outreach.

We have got vaccines. We have got more vaccines than we need. But we do not have the people in. They are not only missing the immunization, they are missing the primary and preventive health care which is vitally important. We may have more information on that as a result of the discussions this weekend, but this is something that we would like to work with you on because if the kids are not getting immunized you are darn sure they are not getting the other primary and preventive health care that is so vitally important.

We appreciate your strong support for family preservation and support. We think there are a lot of good things we can do there.

I join in the chorus on LIHEAP. I realize that there are some reforms. You state that the approach is expected to reduce the overall need for LIHEAP assistance now and in the future. I want to see that because LIHEAP is very important to a lot of people in Missouri, as well as Pennsylvania and Arkansas.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bond. I want to strongly support Senator Bond's statement in regard to the vaccines and immunization.

Senator Mack.

OPENING REMARKS OF SENATOR CONNIE MACK

Senator MACK. Thank you, Mr. Chairman. I just welcome the Secretary. I do have some questions that I will pose later. Hopefully, we will get a chance to listen to your testimony.

Senator HARKIN. Thank you, Senator Mack.
 Senator Cochran.

OPENING REMARKS OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, I have an equally long statement to make.

I welcome you to our committee, and I am going to submit some questions to you about the State Offices of Rural Health and Healthy Start Program, particularly, with the interest we have in Mississippi for that program. And we wish you good luck in trying to get the funding to allocate to all these very worthwhile programs that you administer.

Senator HARKIN. The Chair is most grateful. Thank you very much, Senator Cochran.

Senator Gorton.

OPENING REMARKS OF SENATOR SLADE GORTON

Senator GORTON. I will echo the remarks of Senators Mack and Cochran and will have either questions orally or in writing later at a more appropriate point.

Senator HARKIN. Thank you, Senator Gorton.

Senator Kohl.

OPENING REMARKS OF SENATOR HERB KOHL

Senator KOHL. I, too, am very pleased to see you here today, and I will not introduce any kind of a long statement. I am just happy to have you here and would like to talk about LIHEAP and medical fraud that occurs in the private sector which is pushing up the cost of health care for everybody.

I want to talk to you about extending Federal jurisdiction over fraud in the private sector, but I am looking forward to having a chance to talk to you later on this morning.

Thank you very much.

SUMMARY STATEMENT OF SECRETARY DONNA SHALALA

Senator HARKIN. Madam Secretary, welcome. Please proceed as you so desire.

Secretary SHALALA. Thank you very much, Mr. Chairman, and members of the subcommittee, thank you for inviting me here today to discuss the Department of Health and Human Services' portion of the 1995 budget of the President.

This year's budget has been described as one of the toughest ever sent to Congress. I thought I would use the time I have with you today to outline some of our thinking in developing our own tough budget plan for 1995.

Putting together this budget was no easy process. It was, in fact, not only professionally painful for us but also personally painful for us. The 1995 zero sum game forced two basic options, either straight-lining everything or making the difficult choices to shrink our lowest priorities in order to boost our highest. We decided on the latter. Our budget reflects a deliberate decision to sharpen our focus and advance our best investments.

In 1995, we concentrated on moving forward on three fronts: children, prevention, and customer service. We believe these are the most important investments we can make. For 1995, the President is proposing \$33 billion in budget authority for HHS discretionary programs falling under the purview of this subcommittee. This is an increase of \$1.5 billion or 5 percent over last year's level. Our budget provides sizable expansions for critical HHS investments with proven rates of success, investments aimed at improving the lives of our children, enhancing our understanding and prevention of disease, and expanding our efforts to reduce substance abuse among hard-core users, in addition, strengthening our support for those with HIV/AIDS and bettering service for our customers.

We believe that these increases are in line with and, in fact, build from what you were able to accomplish under the tight constraints you faced in 1994. We have worked to sustain our commitments to these investments. In 1995, our plan calls for the Health and Human Service investment budget to grow by more than \$2 billion or 10 percent. That is twice the rate of our overall budget growth. I would like to highlight some of our key investment increases for you and why we believe they are important.

First, let us begin with children. For Head Start we are proposing a \$700 million increase, or a 21-percent growth. With this investment we will be able to serve up to 840,000 and their families in 1995 while moving forward on the recommendations of the Bipartisan Advisory Committee on Head Start Quality and Expansion.

Head Start continues to be the most successful preschool and family support program in the history of this country. We must keep it strong. But more important, we must make it strong.

At least 25 percent of our proposed increase for Head Start will be invested in critical quality improvements, helping steer us toward our goal of a refocused, reenergized, and different 21st century Head Start Program. It must be a program that meets real and changing needs of the families and the communities it serves.

Our budget also includes a \$172 million increase for the child care and development block grant. This expansion of nearly 20 percent will support more parents in getting care they need to pursue work or job training, a critical component of our longer-term plans to reform welfare. The increase we have planned will also provide new funding for quality improvements in child care.

In addition, we are proposing \$880 million to support the Department's immunization activities, including the launch of our brand new Vaccines for Children Program. This program will finally enable this country to improve its dismal record on childhood immunization. Along with providing vaccines, our request supports the build-up of State and local delivery systems which is the most critical component of our vaccine effort: More clinics, more hours, more health professionals, and more outreach. Immunizations help prevent sickness and, of course, the tragic loss of young lives. But both of the pieces have to be in place: Providing the vaccine, and most important, the build-up of the delivery system. Like other prevention increases, this one is not just cost effective, it is just plain common sense.

Prevention is a major linchpin of all our investment priorities in the Department. In other prevention initiatives, our request includes a 17-percent increase in substance abuse treatment and prevention. Included in this request is a new \$345 million drug abuse and treatment program directed toward hard core users. Hard core users in this country disproportionately fuel drug demand, affect violent crime, and contribute toward the spread of HIV. For example, of all the cocaine users, about 20 percent are hard core users, and they consume about two-thirds of all the cocaine in the United States.

We intend that pregnant women will be at the top of our priority list for this program. Any woman who is pregnant and uses drugs not only endangers herself but she endangers her unborn child. This new initiative will be a special component of the substance abuse block grant and distributed to States using that same basic formula.

Despite this year's budget constraints, the President has not neglected his commitment to strengthen and support those infected with HIV, and this budget provides an overall increase of 7 percent for the Public Health Service's AIDS program. Funding for AIDS programs across HHS and across other Federal programs will rise by 10 percent. In addition to the research dollars we have committed, our request of \$672 million for Ryan White represents an increase of \$93 million or 16 percent for HIV/AIDS services.

For the National Institutes of Health, an agency critical in advancing our understanding and treatment of disease as well as central to our health reform efforts, our budget provides a 4.9-percent increase. Over the past 2 years we will have increased NIH by 11 percent, a major gain. Within the NIH total, our \$535 million add-on will allow us to advance our efforts in basic research, as well as to move forward on key initiative areas such as women's health, breast cancer, and AIDS research.

CUSTOMER SERVICES

To continue our investment in Social Security we have provided \$329 million more than last year's appropriation in 1995. This level will allow SSA to control growth in disability backlogs and begin to strategically move forward in its plans to fundamentally re-engineer the disability process. This means completely rethinking the way we do our business to improve Social Security services to our applicants and to enrich the jobs of our employees. Rather than going down, SSA staffing will go up. More money, more employees, better management, and better technology is the best strategy for improving service to the millions of Americans who benefit from our great Social Security program.

HEALTH CARE AND WELFARE REFORM

In addition to these initiatives, we have, of course, those major initiatives, and our 1995 budget anticipates the enactment of the most important piece of domestic legislation in this century, the President's Health Security Act. The Health Security Act proposes \$1.1 billion in 1995 for public health initiatives related to health care reform. These include increased support for community and

migrant health centers and improved access to public health and underserved urban and rural Americans.

Our budget also anticipates welfare reform, which joins health care reform as a defining issue. Our Head Start and child care investments are early down payments on welfare reform. This spring we will send you our plan to end welfare as we know it, scrapping a system that has discouraged work, fostered dependence, and undermined families, and replacing it with a system that is rooted in fundamental American values of work and responsibility.

I want to emphasize again that our investment increases do not come without a price. As I indicated before, we were able to finance them only by looking very critically at our base and finding a reasonable path for those programs as well. This means determining ways to reduce costs and eliminating duplication.

Our 1995 budget continues along the path started last year by reducing the Department's personnel rolls. The 2-percent cut we will achieve by the close of 1995 reflects a reduction of more than 2,200 FTE's since 1993. Consistent with our larger budget design, our FTE reductions are applied in a way to preserve progress in our investment programs. Social Security, for example, will grow by 400 FTE through 1995, despite the Department's overall FTE reduction.

We have put forth many program consolidations that make good common sense, 51 in all. These are across the Department—in the Administration for Children and Families, the Substance Abuse and Mental Health Services Administration, and in the health professions.

Eighty-six of the Department's programs are frozen in 1995, and seven major programs are cut by over \$1 billion. For example, we did propose a \$745 million decrease in the low-income home energy assistance program. LIHEAP, as you know, was created to help low-income families deal with drastic increases in home energy cost caused by the 1970's oil embargo. We believe that today's energy situation warrants a rethinking of our approach for LIHEAP.

While preserving part of the program, we are addressing poverty in a more comprehensive fashion. With programs like the expanded earned income tax credit, we intend to improve overall economic self-sufficiency rather than relying on categorical assistance that is not very well targeted.

We look forward to working with you and with others in Congress to create a smarter LIHEAP program for the future, a LIHEAP that provides long-term solutions for those low-income Americans with the heaviest energy burdens.

I realize a budget that sets key priorities and finances them through reductions in other programs will be painful to adopt. I would just like to close by asking you to think about it in the way we did.

Last year, many of you cast a very difficult vote to freeze spending for the next 5 years in order to accommodate the larger goal of reducing the deficit. Though difficult, this action will ultimately allow for a stronger economy and a brighter future for our children. In forming a budget amidst 1995's spending freeze, we, too, were faced with very tough choices. We made funding decisions that we believe best support our broader goal of reversing a long-neglected

investment deficit, focusing significant increases on those areas which hold the best promise for a better tomorrow for our children and families.

PREPARED STATEMENT

I am certainly looking forward to working with each of you again this year in settling on the best possible budget strategy for the Department, and I would be happy to answer any questions you might have.

[The statement follows:]

STATEMENT OF SECRETARY DONNA E. SHALALA

Mr. Chairman and Members of the Subcommittee, thank you for inviting me here today to discuss the HHS portion of the 1995 President's Budget. This year's budget has been described as "one of the toughest" ever sent to Congress.

I thought that I would use the time I have with you today to outline our thinking in developing our own tough budget plan for 1995.

Putting together this budget was no easy process. The 1995 zero sum game forced two basic options: straightlining everything, or making the difficult choices to shrink our lowest priorities in order to boost our highest. We decided on the latter.

Our budget reflects a deliberate decision to sharpen our focus and advance our best investments. In 1995, we concentrate on moving forward on three fronts—children, prevention and customer service. We believe these are the most important investments we can make.

For 1995, the President is proposing \$33 billion in budget authority for HHS discretionary programs falling under the purview of this Subcommittee. This is an increase of \$1.5 billion, or 5 percent, over last year's level.

Our budget provides sizable expansions for critical HHS investments with proven rates of success—investments aimed at improving the lives of our children; enhancing our understanding and prevention of disease; expanding our efforts to reduce substance abuse among hard core users; strengthening our support for those with HIV/AIDS; and bettering service for our customers.

We believe that these increases are in line with, and in fact, build from, what you were able to accomplish under the tight constraints you faced in 1994. We have worked to sustain our commitments to these investments.

In 1995, our plan calls for the HHS investment budget to grow by more than \$2 billion, or 10 percent—that's twice the rate of our overall budget growth. Let me highlight some of our key investment increases for you and why we believe they're important:

CHILDREN

First, for Head Start, we are proposing a \$700 million increase, or 21 percent growth. With this investment, we will be able to serve up to 840,000 children and their families in 1995, while moving forward on the recommendations of the bipartisan Advisory Committee on Head Start Quality and Expansion.

Head Start continues to be the most successful pre-school and family support program in the history of this Nation. We must keep it strong.

At least 25 percent of our proposed increase for Head Start will be invested in critical quality improvements—helping steer us toward our goal of a refocused, reenergized, and different 21st Century Head Start program. It must be a program that meets real and changing needs of the families and communities it serves.

Our budget also includes a \$172 million increase for the Child Care and Development Block Grant. This expansion—of nearly 20 percent—will support more parents in getting care they need to pursue work or job training, a critical component of our longer-term plans to reform welfare. The increase we've planned will also provide new funding for quality improvements in child care.

In addition, we are proposing \$888 million to support the Department's immunization activities, including the launching of our brand new "Vaccines for Children" program. This program will finally enable America to improve its dismal record on childhood immunization. Along with providing vaccines, our request supports the build-up of State and local delivery systems—more clinics, more hours, and more health professionals. Immunizations help prevent sickness and the tragic loss of young lives. Like our other prevention increases, this one is not just cost effective, it's just plain common sense.

PREVENTION

Prevention is a major linchpin of all our investment priorities. In other prevention initiatives, our request includes a 17 percent increase in substance abuse treatment and prevention.

Included in this request is a new \$345 million drug abuse treatment program directed toward "hard-core" users. Hard-core users disproportionately fuel drug demand, affect violent crime, and contribute toward the spread of HIV. For example, of all cocaine users, about 20 percent are hard-core users, and they consume about two-thirds of all cocaine in the U.S.

Pregnant women will be at the top of our priority list. Any woman who is pregnant and uses drugs not only endangers herself, she endangers her unborn child. This new initiative will be a special component of the Substance Abuse Block Grant and distributed to States using that same basic formula.

Despite this year's budget constraints, the President has not neglected his commitment to strengthen support for those infected with HIV. This budget provides an overall increase of 7 percent for PHS AIDS programs. Funding for AIDS programs across HHS and across other federal programs would rise by 10 percent. In addition to the research dollars we've committed, our request of \$672 million for Ryan White represents an increase of \$93 million or 16 percent.

For the National Institutes of Health, an agency critical in advancing our understanding and treatment of disease, as well as central to our health reform efforts, our budget provides a 4.9 percent increase. Over the past two years, we have increased NIH by 11 percent—a major gain. Within the NIH total, our \$535 million add-on will allow us to advance our efforts in basic research, as well as move forward on key initiative areas, such as women's health, breast cancer, and AIDS research.

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To continue our investment in Social Security, we have provided \$329 million more than last year's appropriation in 1995. This level will allow SSA to control growth in disability backlogs, and begin to strategically move forward on its plans to fundamentally re-engineer the disability process. This means completely re-thinking the way we do our business to improve services to our applicants and to enrich the jobs of our employees. Rather than going down, SSA staffing will go up. More money, more employees, better management and better technology is the best strategy for improving service to the millions of Americans who benefit from our great Social Security program.

HEALTH CARE AND WELFARE REFORM

In addition to these initiatives, we have major initiatives in reforming our health care and welfare systems. Our 1995 budget anticipates enactment of the most important piece of domestic legislation in this century—the President's Health Security Act. The Health Security Act proposes \$1.1 billion in 1995 for public health initiatives related to health care reform. These include increased support for Community and Migrant Health Centers and improved access to public health for underserved urban and rural Americans.

Our budget also anticipates welfare reform, which joins health care reform as a defining issue. Our Head Start and Child Care investments are early down-payments on Welfare Reform. This Spring, we will send you our plan to end welfare as we know it—scrapping a system that has discouraged work, fostered dependence, and undermined families—and replacing it with a system that is rooted in the fundamental American values of work and responsibility.

THE PRICE FOR OUR INVESTMENTS

I want to emphasize again that our investment increases did not come without a price. As I indicated before, we were able to finance them only by looking very critically at our base and finding a reasonable path for those programs as well. This meant determining ways to reduce costs and eliminate duplication.

Our 1995 budget continues along the path started last year by reducing the Department's personnel roles. The 2 percent cut we'll achieve by the close of 1995 reflects a reduction of more than 2,200 FTE since 1993. Consistent with our larger budget design, our FTE reductions are applied in a way to preserve progress in our investment programs. SSA, for example, will grow by 400 FTE through 1995, despite the Department's overall FTE reduction.

We have put forth many program consolidations that make good common sense—fifty-one in all. These are across the Department—in the Administration for Children and Families, the Substance Abuse and Mental Health Services Administration and in Health Professions.

Eighty-six of the Department's programs are frozen in 1995. And seven major programs are cut—by over \$1 billion.

For example, we are proposing a \$745 million decrease to the Low Income Home Energy Assistance Program. LIHEAP, as you know, was created to help low-income families deal with drastic increases in home energy costs caused by the 1970's oil embargo. We believe that today's energy situation warrants a re-thinking of our approach for LIHEAP. While preserving part of the program, we are addressing poverty in a more comprehensive fashion—with programs like the expanded earned income tax credit. We intend to improve overall economic self-sufficiency rather than relying on categorical assistance that is not well targeted. We look forward to working with you and others in Congress to create a smarter LIHEAP program for the future—a LIHEAP that provides long-term solutions for those low-income Americans with the heaviest energy burdens.

I realize a budget that sets key priorities and finances those through reductions in other programs will be painful to adopt. I would just like to close by asking you to think about it in the way we did.

Last year, many of you cast a very difficult vote to freeze spending for the next five years in order to accommodate the larger goal of reducing the deficit. Though difficult, this action ultimately will allow for a stronger economy and a brighter future for our children.

In forming a budget amidst 1995's spending freeze, we too were faced with very tough choices. We made funding decisions that we believe best support our broader goal of reversing a long-neglected investment deficit, focusing significant increases on those areas which hold the best promise for a better tomorrow for our children and families.

I am certainly looking forward to working with each of you again this year in settling on the best possible budget strategy for HHS and I would now be happy to answer any questions that you might have.

LIHEAP

Senator HARKIN. Madam Secretary, thank you very much. I am now informed the votes will start at 10:10 a.m. and there will be three 15-minute votes back-to-back, starting at 10:10 a.m.

Madam Secretary, let me just try to concisely ask the first question, and it concerns LIHEAP. As you can see, it is of great interest among a lot of people on this subcommittee as, I am sure you will find, in the entire Congress.

As you pointed out, it was a reaction to the oil embargo of the 1970's, but I think there has been some misinformation, perhaps, that has circulated on the LIHEAP program. The first is that somehow because oil prices are down, that we can afford to cut back on the LIHEAP program. Well, that may be true for oil, but it certainly is not true for natural gas; 52 percent of those participating in the LIHEAP program use natural gas, only 11 percent use heating oil; and natural gas prices, rather than going down, as a matter of fact have gone up over the last few years.

Second, on the eligibility, if you see on the right-hand chart there, the households eligible on the top line, you will see the households served on the bottom line, and of course that dotted line means we are going down even further in the number of households that are served.

You say we need the better target, the LIHEAP program, but according to HHS's own reports, LIHEAP only serves about 23 percent of eligible households. As the chart shows, that is going down if we take that \$700 million cut, and right now 70 percent of household recipients have incomes of less than \$8,000 per household. I

am not certain how you target any better than that. The average payment for LIHEAP is \$215.

So I guess my question is, No. 1, will you take a closer look at the gas prices, and second, does it not also mean that LIHEAP is already targeting the households that are most in need, if over 70 percent goes to households with less than \$8,000? How do we target it any better than that?

Secretary SHALALA. Senator, let me give you a couple of answers.

I was very careful not to get deeply involved in what has happened to energy prices, whether it is oil prices or electrical prices. This is really a fundamental discussion about how best to provide resources for low-income people in this country. Should we have a targeted program for a specific problem like heat addressed by giving people a check to help them pay those bills? Should a larger percentage of that money be used toward leveraging other contributions by the energy companies? Or should we help to fix up their homes with more weatherization through a long-term program?

Or even more fundamentally, from our point of view, whether we ought to do some things that deal with the income of the population that we are talking about. I suggest that the earned income tax credit is a far more effective tool for dealing with the fundamental income problems of this population, particularly for an ongoing problem that is basically an income problem.

The question is whether the bureaucracy should support a narrowly targeted program or deal overall with the income in the population. By dealing through their earned income tax credit rather than with a narrowly targeted program at the national level, I would suggest that we were more helpful to a larger group of low-income people who had some income, but not enough to cover their energy bills.

This is a painful decision for myself and my Department. I am in no way suggesting that taking money away from low-income people is ever a good idea. The question remains as to the best way to help that population. We are simply suggesting that the earned income tax credit now in place as a substitute for a more categorical, narrowly targeted program.

Senator HARKIN. And that just came in last year, so we are just now starting to feel the effects.

Secretary SHALALA. Yes; much larger amounts of money going to the same population as a way of dealing with these issues.

Senator HARKIN. I would turn to Senator Specter here. I know we are going to have to go vote.

Senator SPECTER. Thank you very much, Mr. Chairman.

I associate myself with the comments made by the chairman, Madam Secretary, and will not delve into that subject further, but would like to turn to a couple of subjects which I have had a great deal of constituent inquiry on, and they relate to some areas somewhat broader than the confines of the appropriations process, but ones that I would like to inquire into.

There has been a great deal of concern about the availability of mammograms under the President's proposal for health care, and that, of course, does impact on some aspects of our budget planning here.

The studies that are most impressive to me are the ones which make a mammogram available on an annual basis for women who are under 50, and there has been some conflict apparently in some of the reports of testing. My question to you is twofold. What do you think the preponderance of the evidence is on the necessity for testing on mammograms? What do you anticipate the President's program will end up with on the recommendation from the administration?

Secretary SHALALA. The President's Health Security Act in the comprehensive benefit package recommends mammograms available to all women when requested. The difference is for women over 50, and for women in a high risk group. Their mammograms are provided free. For other women, on request their mammograms would be provided on a cost-sharing basis.

Senator SPECTER. Over 50?

Secretary SHALALA. I'm sorry—for women under 50 who are not in a high risk group. That reflects the scientific evidence as reviewed by the National Cancer Institute. Let me repeat, mammograms would be available to every woman. The difference would be some cost-sharing versus their availability as part of the prevention package. The prevention package reflects the scientific evidence; which concludes that mammogram screening is essential to every woman over 50 and every woman identified in a high risk group.

Finally, as you know, Senator, we are getting closer and closer to being able to identify what women are at risk through a simple test developed through the human genome project. We may well have established evidence that a much larger group is at risk. The population of women who will be covered as part of the prevention package may well increase as part of our overall efforts to improve and provide the benefit package to high risk candidates.

Senator SPECTER. Madam Secretary, I would urge a second look at the issue. There is just enormous concern among women under 50, as well as those over 50, about the availability of annual mammogram testing. I visit Pennsylvania hospitals with some frequency, and I have found that the machines are not in use during much of the time.

I recently had the experience, as you and I have discussed, about an MRI and found that those machines are not in use, and made a suggestion to the White House that there be consideration to having those tests all night long at a lower cost when people might not be as interested in undertaking them. So I would urge another look to see if there is some way that we might not make mammograms available to all women under 50.

Let me in the next minute take up another subject before we go to vote, and that is the question of abortion availability for poor women under the President's health care program, or perhaps more broadly than poor women, all women. The Congress has spoken in a mixed way during the course of the past year by a vote of 51 to 48, as I recollect it, on a procedural matter. Access to abortion was retained in governmental insurance policies.

For the first time the Congress did not preclude the District of Columbia from having abortion care for poor women. That had

been an annual subject of much debate, so that one came out with a more expansive program for abortion services.

That was contrasted with the Hyde amendment for abortion for poor women, which was roundly defeated 59 to 40 in the Senate, and my question to you—and I have been getting a lot of inquiries on this, and I think it would be useful to have the Secretary speak to this subject. What is your expectation as to how the administration position will end up on availability of abortion services for poor women?

Secretary SHALALA. Senator, we have expressed our view in the President's Health Security Act that reproductive health services, including access to abortions, should be available to every woman—poor, middle class, or rich.

Senator SPECTER. So that is a flat out commitment by the administration, to have that service available?

Secretary SHALALA. Yes.

Senator SPECTER. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Senator Mack was kind enough to say if he could get a few things in maybe we could let you go, Madam Secretary.

Senator MACK. Thank you, Mr. Chairman, and I will not be able to get a few things in. I think, since we are going to have three votes and we are going to be gone 45 minutes it would be improper to keep the Secretary here during that period of time.

I have a list of questions that I really did want to pursue with you this morning and I am sorry that I am not going to have the opportunity to do that. Some of it has to do with, while I am pleased with the increase that the President has proposed and that you have proposed in this budget with respect to the National Institutes of Health, there is a concern that I have with respect to the impression anyways that you are earmarking or suggesting to us that we earmark some funds for some cancer research, particularly breast cancer.

I think I can raise this question without someone taking a shot at me, with my wife Priscilla having survived breast cancer the last 2 years and my mother being a breast cancer survivor, but I am concerned about us getting involved in earmarking either from the President's budget or from our committee. I could make a strong argument about why melanoma ought to see a substantial increase with respect to research.

I frankly would like to see the scientists make the decision about how we allocate dollars for research as opposed to encouraging groups around the country to engage in high political pressure to see that funds are focused from one place to another.

But as I say, given the circumstances, I will submit my questions for the record, and would look forward to your responses.

Secretary SHALALA. Senator, I have testified on both sides of that issue. In my career as the head of a major research university, I have argued strongly against earmarking. As Secretary of HHS and as a woman with much experience watching systems freely decide funding, I saw womens' health left out of concerns.

I believe that Harold Varmus, the new head of the National Institutes of Health, would argue both sides of the question. He spent part of his career trying to do research on breast cancer, in part,

because of a family history on breast cancer. His major discovery on the brain, which won him the Nobel Prize, came out of his breast cancer research.

So while you see the title for some earmarking of funds, whether it is AIDS or breast cancer, much of this basic science research may well give us findings in another area. I would make two arguments. While the Department identifies certain coverage in certain areas and the Congress itself has interest in identification, basic science research often leads to other findings.

Second, for women in particular in this country, I must plead with you that when the system was left to itself, the diseases that affected women were too often left out. There is a need for some course correction here, and we believe we have achieved a balance in what we have submitted. Our fundamental commitment in the Department as well as my personal commitment is that we must get the basic science done. I see no reason why we cannot achieve some balance in that.

Senator MACK. Maybe I will end up missing the vote, and that would be unfortunate, but I want to make—and I believe and agree with much of what you had to say, but when I look at what is happening, for example—and I hated to get into this kind of a conversation with a limited amount of time, but I feel it is important to say.

So if you go back to 1986, and you look at least to the numbers I have been given, prostate cancer, for example, there were 90,000 cases, and there are 200,000 cases for 1994, and you look at the number of dollars that are being estimated, \$40 million for research on prostate cancer, \$262 million for—182,000 new cases in breast cancer, \$262 million in breast cancer, and I know that we are going to get benefits from research. One could make the argument, for example, that there will be a tremendous spillover as a result of the investments we are making in AIDS research and many other areas.

But what I am saying to you is, by making a statement about where you would like to see this money spent, we are getting into this business of politics trying to make the decision about where to spend those dollars, and I think that is very, very dangerous, and with that, I have got to go.

Secretary SHALALA. Senator, I would be happy to come by and meet with you and have a longer discussion on this topic.

Senator MACK. I have been asked to recess the subcommittee.

[A brief recess was taken.]

Senator HARKIN. The subcommittee will resume its hearing.

I would now like to welcome panel 2, the witnesses from the Public Health Service and the Health Care Financing Administration. For the sake of time, I will ask our witnesses to submit their prepared testimony for inclusion in the hearing record and give us a brief summary at this time. I would like to withhold questions until we have heard from all members of the panel.

The panelists from the Public Health Service are Assistant Secretary, Dr. Phil Lee; Dr. Sumaya, who is the Administrator of Health Resources and Services Administration; Dr. Satcher, who is the Director of the Centers for Disease Control and Prevention; Dr.

Elaine Johnson, Acting Administrator of the Substance Abuse and Mental Health Services Administration.

From the Health Care Finance Administration, Mr. Bruce Vladeck, the Administrator, is here, and I think I got everybody.

PUBLIC HEALTH SERVICE

STATEMENT OF PHILIP R. LEE, M.D., ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY FOR HEALTH MANAGEMENT OPERATIONS

W. HARELL LITTLE, DIRECTOR, DIVISION OF PHS BUDGET, OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

WILLIAM R. BELDON, DIVISION DIRECTOR, OFFICE OF BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. We will begin with you, Dr. Lee. Please proceed with the highlights of your testimony. Welcome back.

Dr. LEE. Thank you very much, Mr. Chairman. I would like to submit for the record two statements, one that relates to the appropriation requests for the entire Public Health Service, and then a second that relates specifically to the Office of the Assistant Secretary for Health.

Let me say a few things about our request. We are requesting \$19.1 billion in discretionary budget authority for agencies under this committee's jurisdiction. This represents an increase of \$811 million, or 4.4 percent over fiscal year 1994. This is a modest increase, but I think significant in relation to the budgetary caps that have been agreed upon by the Congress and the administration. And thanks to the leadership of this committee, the 1994 appropriation combined with the request for 1995 represents an increase of about 14 percent over 1993.

First, let me say a word about the request for the National Institutes of Health [NIH]. You will be hearing later from Dr. Varmus who will be eloquently describing the sort of enthusiasm he feels for the research advances. And I must say that returning to the Department after serving previously as the Assistant Secretary, I am really astounded at the progress we have made in basic research and where we are in relation to opportunities to advance the health of the American people as a result of this investment. This committee, of course, has been instrumental in sustaining that support over many years.

We have requested a \$535 million, or 4.9-percent increase, for biomedical research activities. Of that, \$282 million will support the basic sciences that have been fundamental to the NIH activities over these many years. The additional funds, although earmarked for priority areas, also include basic research within those areas, such as breast cancer, AIDS research, the human genome research project, and the NIH minority health initiative.

Second, Mr. Chairman, we are requesting \$46 million for immunization infrastructure as a part of the childhood immunization ini-

tiative. This has to be seen in context of the additional funds that are made available through the vaccines for children [VFC] initiative, where the funding is actually being provided by Medicaid and is transferred to the Centers for Disease Control and Prevention [CDC]. That program provides \$424 million. This funding provides a net increase of \$314 million for childhood immunizations that will be used for the purchase of vaccines.

Because of the availability of the Medicaid funds, and because we surveyed the States, we felt that we could reduce discretionary funds by \$110 million for the direct purchase of vaccines under section 317 of the Public Health Service Act. And in response to your request with respect to this proposal, we are continuing to look at this issue. We have received new reports from the States, and we are examining ways in which we can make sure that we meet State needs and we will be reporting back to you very soon about that.

We are also requesting an additional \$93 million for Ryan White HIV/AIDS services and a \$345 million increase for hard core substance abuse programs. This would provide about 74,000 increased slots for hard core drug abusers.

The budget this year, as you know, is going to be very difficult. We had to make some very difficult choices. There were areas where we were not able to propose increases that we hoped to make because of those stringencies. We believe this is a very good budget and that we can achieve common objectives with the Congress.

And I would note that the 1995 budget also includes the President's request for the Health Security Act, including \$1.1 billion for PHS programs under title III, which, of course, has been a very high priority for the administration. The development of these proposals was a high priority for my office and for the entire Public Health Service. These reforms will include every agency of the Public Health Service.

CDC will be playing the major role in prevention with the core public health. NIH, of course, will be playing the major role in advancing basic research and prevention research, and the Agency for Health Care Policy and Research [AHCPR] will advance the health services research. The Substance Abuse and Mental Health Services Administration [SAMHSA] and the Health Resources and Services Administration [HRSA] are both playing significant roles in terms of title III. We think this is a very big opportunity, and although we will not be dealing with those issues specifically today, it is something I wanted to bring before you.

PREPARED STATEMENT

I would like to conclude my opening remarks, Mr. Chairman, and say that the others, of course, will submit their testimonies for the record and briefly comment, and then we will be prepared to respond to your questions.

Senator HARKIN. Thank you very much.

[The statement follows:]

STATEMENT OF DR. PHILIP R. LEE

Mr. Chairman and Members of the Committee, I welcome this opportunity to testify on behalf of the President's fiscal year 1995 budget request for the Public Health Service (PHS).

We are requesting \$19.1 billion in discretionary budget authority for agencies under this Committee's jurisdiction. This represents an increase of \$811 million, or 4.4 percent over fiscal year 1994, which is noteworthy considering there is no overall growth in discretionary spending between fiscal year 1994 and fiscal year 1995. While these increases are modest in terms of the longer-run investment perspective, it was necessary to make difficult choices to gain these increases and to maintain many of our programs at the fiscal year 1994 level.

Mr. Chairman, it is also important to note that because of the support that you and your colleagues provided in fiscal year 1994, our request is a 14 percent increase over the fiscal year 1993 level.

We will use these funds efficiently to sustain the fiscal year 1994 investments, and to further expand several of our highest priorities: biomedical research for the National Institutes of Health (NIH); childhood immunizations; health services research for the Agency for Health Care Policy and Research (AHCPR); Ryan White HIV/AIDS services; hardcore substance abuse; and family planning.

BIOMEDICAL RESEARCH

As this Nation's principal Federal biomedical research investment, NIH plays an integral part to improve the health and quality of life of the U.S. population. The basic science pursued by NIH is fundamental to the discoveries and breakthroughs that enable us to extend the human life span through the prevention of such deadly diseases as AIDS, cancer and multi-drug resistant TB. This basic science enables us to improve the quality of life by delaying the onset of diseases such as Alzheimer's and osteoporosis. Other major discoveries create opportunities for new strategies in the diagnosis, treatment and prevention of disease.

Since my last term in this office, changes resulting from biomedical research have been astounding. The investments in this request will result in additional significant advances in health, and benefit the Nation's population both in terms of health and economic competitiveness. Within the NIH budget, selected priorities were identified to address major opportunities.

For NIH, the Nation's premier health research agency, we are requesting a budget totaling \$11.5 billion, a \$535 million, or 4.9 percent increase over fiscal year 1994. This request includes an increase of \$282 million for basic research. In addition, increases are included for certain high priority areas, including \$87 million for breast cancer research, 29 percent more than the fiscal year 1994 level of \$300 million. We are also requesting an increase of \$78 million for AIDS research, a six percent increase over the fiscal year 1994 level of \$1.3 billion. This would provide a 29 percent increase for AIDS research over the last two years. Increasing investment in AIDS research benefits every aspect of this Nation's biomedical research enterprise by contributions to the knowledge base leading to the prevention and cure of disease.

Other high priority areas include: expanding high performance computing (+ \$24 million) to enable the development of clinical applications from basic research discoveries and the deployment of quality health care throughout the U.S.; expanding the Human Genome Initiative, including providing full funding for the intramural research program at the National Center for Human Genome Research to provide NIH with expertise in the latest genome technologies and resources (+ \$23 million); expanding efforts during the third year of the Minority Health Initiative to improve the health status of minorities (+ \$10 million); expanding the Office of Research on Women's Health to support research affecting women across their life-spans (+ \$6 million); and \$6 million to expand research efforts to treat, cure, and prevent the continued spread of TB.

I should note that while the total number of research project grants will remain at approximately the fiscal year 1994 level, the number of new and competing grants will increase to 7,292, 1,089 more than in fiscal year 1994. This is the highest number of new and competing grants ever requested for NIH, and will help to keep the U.S. at the forefront of medical technology development.

PREVENTION—CHILDHOOD IMMUNIZATION

Investing in the health of our children is one of the President's highest priorities. Childhood immunizations are one of our most effective prevention strategies, and our most important childhood disease prevention priority in this budget request. Childhood immunizations reduce illness, deaths, and future medical costs. Two

major barriers to on-time immunizations are access to services, and the cost of the vaccines. The Centers for Disease Control and Prevention's (CDC) budget request includes an additional \$46 million to help States and local governments continue rebuilding and enhancing the Nation's immunization infrastructure. Without this framework, it would be extremely difficult to achieve our goal of providing on-time childhood immunizations for 90 percent of this Nation's two-year old children by 1996.

The \$46 million increase will allow public health clinics and other public providers to hire more personnel, extend clinic hours, improve access by opening more clinics and help us educate and mobilize more parents and health professionals to make sure all children are immunized. In addition to ensuring the good health of our children, we will also ensure future cost savings, since the cost effectiveness and cost savings associated with age appropriate immunizations are well-known.

In order to make sure that childhood vaccines are available, we are proposing to transfer from Medicaid to CDC, a \$424 million Vaccines for Children program. This program, which was authorized by the Omnibus Budget Reconciliation Act of 1993, provides vaccine for those children with no insurance, whose insurance does not cover vaccines, children who are Native Americans, and those children who receive their vaccinations at a Federally qualified health center or rural health center.

Because of the availability of funding under the Vaccines for Children (VFC) program, CDC has proposed to reduce its discretionary budget for vaccine purchases by \$110 million in fiscal year 1995. On a comparative basis, we expect PHS childhood vaccine purchases to increase from \$192 million to \$506 million, an increase of \$314 million.

HEALTH SERVICES RESEARCH

For AHCPR, we are requesting a program level of \$173 million, a \$19 million, or 12 percent increase over fiscal year 1994. The AHCPR budget supports expansion of the National Medical Expenditure Survey and increased research on health care reform issues such as: cost and financing of health care; primary care and its potential to improve health through timely access to care while reducing health care cost; quality improvement; medical liability; and AIDS. These activities will provide policy makers, health care professionals, and the public with the information and analysis needed to evaluate the current health care system, selected medical practices and their outcomes, and health care reform measures.

RYAN WHITE HIV/AIDS SERVICES

We are requesting an increase of \$93 million in the Health Resources and Services Administration (HRSA) for HIV/AIDS service programs funded under the Ryan White Act. This increase includes: \$39 million for emergency funding to cities that will not only support the 34 current areas at the fiscal year 1994 level, but will also provide for 3 to 7 new areas in fiscal year 1995; \$30 million for a 16 percent increase to comprehensive care grants to states to support HIV planning and service activities, drug reimbursement and assistance to a growing number of underserved people who have no other access to critical treatment; \$19 million, or a 40 percent increase for early intervention activities that will provide services to an additional 38,100 people at risk of HIV infection; and \$5 million to support an additional 10 pediatric and adolescent AIDS demonstration projects that will develop models of comprehensive care systems—linked to research—for children, adolescents, women, and families.

HARDCORE SUBSTANCE ABUSE TREATMENT

Recognizing the strong linkage between hardcore substance abuse and its health and crime consequences to society, the President's Budget proposes increasing funds for substance abuse treatment to a record level. This budget places significant effort on demand reduction programs, particularly treatment services for hardcore users. This will also impact other health initiatives, such as HIV/AIDS prevention.

We are proposing an increase of \$345 million for the Substance Abuse and Mental Health Services Administration (SAMHSA), and \$10 million in the Indian Health Service for a new hardcore substance abuse treatment initiative that will provide treatment slots for approximately 74,000 hardcore substance abusers. This increase will target chronic, hardcore substance abusers, the heaviest users who put great strains on our society in the form of increased crime, health costs and homelessness. Most of these funds (\$310 million) will be distributed through the current Substance Abuse Treatment block grants. In addition, \$35 million will be distributed on a competitive basis through a new SAMHSA hardcore treatment demonstration program

that focuses on developing and testing models for integrating severe addiction service systems into primary health and specialty substance abuse treatment systems.

PROGRAM CONSOLIDATIONS

In order to simplify some grant processes and ease the paperwork burdens on the States and other grantees, as well as reduce some Federal costs, certain agency grant programs were consolidated. These consolidations will provide grantees with more flexibility in directing their resources, and will enable the grantees and us to reduce administrative costs and associated staffing.

Within HRSA, we are working toward consolidating a number of categorical health professions programs to reduce the administrative burden on educational institutions and on the Federal government, while increasing flexibility.

Within CDC, we have already consolidated many HIV/AIDS prevention categorical grants. This will allow states and communities to develop and implement integrated community plans directed toward the prevention of HIV and improve operational effectiveness.

In SAMHSA, we are proposing to consolidate the multiple demonstration authorities in each SAMHSA center into a single authority for each center. This consolidation will reduce the number of discrete grant announcements, simplify application procedures and improve the efficiency of the grant review process.

HEALTH CARE REFORM

Since becoming the Assistant Secretary for Health, I have had the opportunity to testify before numerous Congressional subcommittees and committees on issues relating to the President's Health Security Act. This Act is unique among the proposals before Congress to reform the personal health care system and revitalize the public health system to improve the health of the population and help to control the rising personal health care costs. It emphasizes prevention. It makes health plans accountable to achieve prevention and public health objectives. It fosters a close working relationship among research, clinical care and public health. Title III of the Health Security Act embodies the major elements of Health Care Reform affecting the Public Health Service. The programs in the Public Health Initiative would: strengthen the capability of communities to improve the health of their populations and address high-priority local health problems; improve the knowledge base for preventing disease and providing medical care more appropriately and efficiently; and assure access to necessary health services for all Americans, particularly low-income, isolated, hard-to-reach populations.

The proposed legislation will support a prevention research initiative for NIH. This will provide a knowledge base to prevent disease and promote health more effectively. Expanded prevention research will help ensure the future availability of effective preventive measures against existing disease, as well as new and emerging health threats. Progress in preventing disease will help to offset escalating acute health care costs and the disproportionate impact of disease and disability among women, minorities, and the elderly.

However, the budget request before you today does not include the \$1.1 billion in funding related to these proposals.

PHS LEADERSHIP

In concluding, I would like to comment on PHS leadership and the OASH role. This is a very challenging time for PHS leadership. The Assistant Secretary for Health provides the executive leadership, coordination, and direction of the PHS to ensure that programs are carried out in accordance with overall policy and legislative directions. To do this, the Assistant Secretary's office focuses on the activities that "only we can do"—to lead in developing policies and establishing priorities within the PHS; coordinating the implementation of priority initiatives across PHS; providing technical direction to and facilitating the work of individual agencies; ensuring collaboration across agencies and within DHHS on cross-cutting programs; and monitoring performance and accountability for achieving overall PHS goals. We also work closely with the Secretary, White House, the Congress, and outside organizations regarding policies and priorities to promote the goals of PHS (as enunciated in Healthy People 2000) with respect to improving the health of the U.S. population with special emphasis on the disadvantaged.

The Assistant Secretary is also managing the overall PHS effort in response to the Vice-President's National Performance Review and the Department's Continuous Improvement Program. Our efforts include an aggressive review of administrative policies and practices, including regulation practices, delegating additional functions

to the agencies, and reviewing personnel, budget, contracting and other administrative activities.

Mr. Chairman, that concludes my opening remarks. I would be pleased to answer any questions that you and the Committee members may have.

BIOGRAPHICAL SKETCH OF PHILIP R. LEE, M.D.

Department of Health and Human Services Assistant Secretary Philip Randolph Lee, M.D., leads the U.S. Public Health Service at a time when this country's major national issue is health care reform—how to promote the health of the public through health care reform, how to assure universal access, how to assure quality, how to contain rapidly rising costs and how to pay for it. The programs of the Public Health Service that Dr. Lee will direct contribute to virtually all those objectives.

Dr. Lee was sworn in as HHS Assistant Secretary for Health on July 2, 1993, after being nominated by President Clinton May 18, 1993, and confirmed by the Senate July 1, 1993.

Dr. Lee brings to his new post more than four decades of involvement in health care and public health policy.

Twenty-eight years ago (November 1965), Dr. Lee was sworn in as Assistant Secretary for Health and Scientific Affairs under President Johnson. In his first two years as Assistant Secretary, from 1965 to 1967, Congress enacted more health legislation than all the previous Congresses put together. Not since that period has the public's health and health care reform been such a huge priority on the nation's agenda.

Among his activities as Assistant Secretary of the Public Health Service in the 1960's, Dr. Lee helped fashion health manpower, family planning, health care, consumer protection, environmental health and biomedical research policies.

Before his first appointment to the top Public Health Service role, Dr. Lee served as Director of Health Services in the Agency for International Development. Prior to his government service, he was a staff member at the Palo Alto Medical Clinic in California, and before that a fellow at the Mayo Clinic and Bellevue Medical Center. Dr. Lee's clinical experience enhances his commitment to public health policy and improving both care and access to care.

Dr. Lee has served with distinction as Director of the Institute of Health Policy Studies, School of Medicine at the University of California, San Francisco for the past twenty-one years. In these years, he has, as a colleague recently said, worked with and influenced hundreds of health care policymakers and researchers, many of whom name Dr. Lee as their mentor. Since 1969, Dr. Lee has been a Professor of Social Medicine at UCSF.

Dr. Lee has frequently advised federal and state health groups, and served on numerous advisory boards and planning committees. In 1985, San Francisco Mayor Dianne Feinstein named him as the first president of the city's Health Commission, which was the governing body in the city/county health department that included public health, mental health and substance abuse services, as well as the San Francisco General Hospital (the major AIDS care facility in the city), and a 1,000-bed long-term care facility.

In 1986, when Congress set up the Physician Payment Review Commission to examine reimbursement of physicians under Medicare, Dr. Lee was named to head the Commission. The Commission worked closely with Congress and many physician groups, consumer groups and others in shaping the physician payment reform adopted by Congress in 1989. Dr. Lee resigned from the Commission early this year after being asked by President Clinton to serve as Assistant Secretary for Health.

Until 1993 and his confirmation as Assistant Secretary, Dr. Lee served on the Board of Trustees of several California-based organizations representing a variety of public interests: the Henry J. Kaiser Foundation, Jenifer Altman Foundation, World Institute on Disability, and the Glide Foundation of the Glide Memorial United Methodist Church. Also, from 1971 to 1979 Dr. Lee served on the Board of Trustees of the Carnegie Corporation of New York.

Dr. Lee was a member of the editorial boards of the health policy journal *Milbank Quarterly* and of the *Annals of Internal Medicine* until assuming his recent Public Health Service responsibilities.

The Public Health Service that Dr. Lee directs today includes eight agencies that lead the world in health care for the underserved, in biomedical research, in food and drug safety and in disease control. These agencies are the National Institutes of Health, The Centers for Disease Control and Prevention, the Food and Drug Administration, the Agency for Toxic Substances and Disease Registry, the Health Resources and Services Administration, the Indian Health Service, the Substance

Abuse and Mental Health Services Administration, and the Agency for Health Care Policy and Research.

Also located in the Office of the Assistant Secretary are the Office of the Surgeon General, the National Immunization Program Office, the Office of Population Affairs, the Office of Minority Health, the Office of Women's Health, the Office of Disease Prevention and Health Promotion, the Office of International Health and the National AIDS Program Office.

Dr. Lee also advises and assists HHS Secretary Donna Shalala on health policy and on all health-related activities of the Department. He has played an active role in the health care reform task force.

Dr. Lee received an A.B. from Stanford University in 1945, an M.D. from Stanford in 1948, an M.S. from the University of Minnesota in 1955, and an honorary Sc.D. from MacMurray College in 1967.

Dr. Lee lives in Washington, D.C. His wife, Professor Carroll Estes, also of the University of California, is a world recognized expert in aging and long-term care policy. Dr. Lee has five children, a stepdaughter and five grandchildren.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
STATEMENT OF CIRO V. SUMAYA, M.D., M.P.H.T.M., ADMINISTRATOR

BUDGET REQUEST

Senator HARKIN. We will now turn to Dr. Sumaya, Administrator of the Health Resources and Services Administration.

Dr. SUMAYA. Mr. Chairman, I am pleased to appear today to discuss the fiscal year 1995 budget for the Health Resources and Services Administration, or HRSA. This is my second month as the HRSA Administrator. Previous to this I was the associate dean for affiliated programs and continuing medical education at the University of Texas Health Science Center at San Antonio, TX.

Our budget request of over \$3 billion continues the Agency's preeminent role in providing primary health care and health profession education to better serve the underserved and the disadvantaged. The focus of this year's budget is the continuation of the President's investment initiative for the Ryan White AIDS Program.

For HRSA, we are requesting an additional \$93 million, a 16-percent increase above the 1994 appropriation. The elements of this proposal are:

A \$39 million, or 12 percent increase, in HIV emergency relief grants, providing funds to an estimated 37 to 41 cities.

A \$30 million, or 16 percent increase, for part B of the Ryan White Emergency Act of 1990, providing funds to States and territories for the operation of HIV service delivery consortia in the localities most affected by the epidemic, for the provision of home- and community-based care, for continuation of insurance coverage for infected people, and for HIV treatments that prolong life and prevent serious deterioration of health.

A \$19 million, or 40 percent increase, for early intervention services providing grants to federally qualified health centers and non-profit private entities that provide comprehensive primary care services to populations at risk of HIV disease.

And a \$5 million, or 23 percent increase, for part D, which sponsors demonstration grants to ensure that clinical research and outpatient health care are accessible and coordinated for the target population of HIV-infected children, pregnant women, and their families.

The budget request also includes an \$18 million, or 10 percent increase, for family planning to provide outreach services to low-income women, to place more emphasis on prevention of teen pregnancy, and on training and retention of family planning nurse practitioners, to increase the focus of quality and completeness of services, and to expand current clinic sites and development of clinics in high-need areas; and a proposal to consolidate the health profession's authorities in five consolidated programs. This is consist-

ent with the Vice President's National Performance Review Task Force to consolidate and refocus existing health profession's education programs to meet needs for primary care providers, health professionals for underserved areas and populations, and minority health professionals.

The remaining programs in HRSA will be maintained at the fiscal year 1994 level. This will meet our commitments to improving the Nation's primary health care to community and migrant health centers, treatment programs for persons with black lung disease, Hansen's disease, and AIDS, and a wide variety of other activities dealing with organ transplantation, vaccine injury compensation, and health care services for the homeless.

PREPARED STATEMENT

In fiscal year 1995, the Health Resources and Services Administration will address many opportunities and numerous challenges, and I believe the budget we are presenting to you will enable us to take advantage of these opportunities and meet these challenges.

At this time, Mr. Chairman and members of the committee, I would be pleased to answer any questions you may have.

Senator HARKIN. Thank you very much, Dr. Sumaya.

[The statement follows:]

STATEMENT OF DR. CIRO V. SUMAYA

Mr. Chairman and Members of the Committee, I am pleased to appear before you today to discuss the fiscal year 1995 budget request for the Health Resources and Services Administration (HRSA). This is my second month on the job as the HRSA Administrator. Previous to this, I was the Associate Dean for Affiliated Programs and Continuing Medical Education at the University of Texas Health Science Center at San Antonio, Texas.

These are challenging times for this agency as the Nation prepares to take on the responsibility of ensuring that comprehensive health care is available to all Americans. HRSA is moving fast to be ready to meet the new challenges.

The fiscal year 1995 budget for HRSA proposes to extend most of our traditional activities at the fiscal year 1994 appropriation level. In total, we are requesting over \$3 billion and 2,054 direct full-time-equivalent positions. Our partners in this effort are State and local health departments, private nonprofit organizations, universities, other Federal agencies, community and migrant health centers, hospitals and other health facilities, private insurers, employers, and many other participants in our nation's public health system. We work hard to coordinate and combine our efforts with our partners to use most effectively the resources available to us.

The focus of this year's budget increase is the continuation of the President's Investment Initiative for the Ryan White AIDS programs and the Family Planning program. For HRSA, this represents an increase of \$93 million (+ 16 percent) above the fiscal year 1994 appropriation for Ryan White and an \$18 million (+ 10 percent) increase for the Family Planning Program. These increases are partially offset by a \$15 million decrease to Health Professions Programs and an \$8 million decrease from the Maternal and Child Health Block Grant set-aside, for a net increase of \$88 million. The elements of this proposal are: an increase of \$93 million above the fiscal year 1994 appropriation for funding of the programs authorized by the Ryan White Comprehensive AIDS Resources Emergency Act of 1990. The HIV epidemic is a multifaceted national and international problem. The HRSA's role in this effort includes support for community based planning, a broad range of primary care and support services, as well as educational and training programs. Specific request amounts include:

- A total of \$364.5 million for HIV Emergency Relief Grants (an increase of \$39 million—or 12 percent—over the fiscal year 1994 appropriation) providing funds to an estimated 37 to 41 metropolitan areas with very high numbers and/or rates of AIDS cases. From 3 to 7 new metropolitan areas will be eligible in fiscal year 1995. These grants fund coordinated outpatient and ambulatory health and social support services;

- \$214 million for HIV Care Grants (an increase of \$30 million—or 16 percent—over the fiscal year 1994 appropriation) providing funds to States and territories for the operation of HIV service delivery consortia in the localities most affected by the epidemic, for the provision of home and community-based care, for continuation of insurance coverage for people with HIV, and for HIV related pharmaceuticals that prolong life and prevent serious deterioration of health;
- \$67 million for Early Intervention Services (an increase of \$19 million—or 40 percent—above the fiscal year 1994 appropriation) provided grants to federally qualified health centers and nonprofit private entities that provide comprehensive primary care services and preventive health services to people with HIV and populations at risk of HIV disease;
- \$27 million (an increase of \$5 million—or 23 percent—above the fiscal year 1994 appropriation) to expand Part D (Title IV) which supports the creation of comprehensive, community based care networks for children, pregnant women, and their families and ensures that clinical research and outpatient health care are accessible and coordinated for these targeted populations; and
- \$199 million (an increase of \$18 million—or 10 percent—above the fiscal year 1994 appropriation) to provide outreach services to low-income women; to place more emphasis on prevention of teen pregnancy and on training and retention of Family Planning nurse-practitioners; to increase the focus of quality and completeness of services; and to expand current clinic sites and development of clinics in high need areas.

In addition to these increases which are included in the President's budget, HRSA programs will continue more than \$2.9 billion in ongoing program activities including CHC's, MHC's, and the NHSC.

COMMUNITY HEALTH CENTERS

The fiscal year 1995 request includes \$604 million, the same as the fiscal year 1994 appropriation, to continue support to about 1,500 Community Health Center sites, providing primary health care services to approximately 6.4 million medically underserved individuals. Residents of underserved communities may not have access to care because they lack insurance, live in communities without sufficient health delivery capacity, have health concerns not met by traditional medical care, or face other barriers to care. The request includes funding for the case management approach to perinatal care designed to reduce infant mortality.

MIGRANT HEALTH CENTERS

The fiscal year 1995 request of \$59 million for Migrant Health Centers will continue primary care services to approximately 550,000 migrant and seasonal farmworkers and their families. This, too, is a group which finds access to health care difficult because of lifestyle, location, language, culture, and economic barriers.

NATIONAL HEALTH SERVICE CORPS (NHSC)

The NHSC program is designed to improve the capacity to provide health services in Health Professional Shortage Areas (HPSA) and improve access to health care in these areas through the placement and support of health professionals. The NHSC, and its related recruitment and retention efforts, play a critical role in the attempt to reduce shortages of physicians and other primary care providers such as nurse practitioners and midwives and physicians assistants in the most difficult to staff areas throughout the country. The budget request of \$44.7 million, the same as the fiscal year 1994 appropriation, will continue logistical and clinical support for the current and projected field strength levels.

NATIONAL HEALTH SERVICE CORPS RECRUITMENT

The fiscal year 1995 budget request of \$79.3 million for NHSC recruitment, the same as the fiscal year 1994 appropriation, will support 417 new scholarships, 418 Federal loan repayments to health professionals and health professions students, and 380 State loan repayment agreements in exchange for service in the neediest HPSAS.

MATERNAL AND CHILD HEALTH

The fiscal year 1995 request is \$679 million for the Maternal and Child Health Block Grant Program (MCH). Given the limits imposed by the discretionary caps, an \$8 million decrease is proposed for the MCH Special Projects of Regional and National Significance (SPRANS) set-aside. The request will enable States to con-

tinue to provide a wide range of health services to mothers, infants and children; particularly those with low income or limited availability of health services, as well as provide community health activities and systems development through setaside programs. While the reduction of \$8 million is targeted to Research and Maternal and Child Health Improvement Projects, all continuations will be funded. The request includes: \$574.5 million for State Block grants; \$93.4 million for special projects of regional and national significance (SPRANS) in the categories of research, training, hemophilia, genetic diseases, and maternal and child health improvement; and \$11.1 million for the Community Integrated Service Systems set-aside which supports the development and expansion of primary care delivery strategies for mothers and children.

HEALTHY START INITIATIVE

The fiscal year 1995 request includes \$97.5 million, the same as the fiscal year 1994 appropriation, to continue the 15 Healthy Start projects. These grants will assist in the provision of comprehensive maternal and infant health care and social services in communities with highest infant mortality rates in order to reduce the rates by half. Healthy Start includes a national public education campaign to publicize simple, practical information on pregnancy and infant health, with special emphasis on high-risk women of childbearing age and prospective fathers. These projects should reach the full scope and intensity of program interventions during this year.

HEALTH PROFESSIONS

The President's budget proposes to consolidate existing multiple categorical grant and contract programs under Titles VII and VIII of the PHS Act into five consolidated programs. Currently, HRSA's health professions programs are characterized by over 30 separate program authorizations. The fiscal year 1995 request recommends consolidating and refocusing existing health professions education programs to meet the Nation's need to increase the supply of primary health care providers, to increase the supply of health professionals for underserved areas, and to increase the supply of minority health professionals.

VACCINE INJURY COMPENSATION PROGRAM

The National Childhood Vaccine Injury Act of 1986 established a program to provide compensation for vaccine-related injury or death. The Administration is requesting \$110 million, the full authorization level, to pay pre-1988 claims. The fiscal year 1995 request seeks \$54 million for payment of post-1988 claims and \$3 million for administrative costs both to be paid from the National Vaccine Injury Compensation Trust Fund.

HEALTH EDUCATION ASSISTANCE LOANS (HEAL)

The HEAL program insures loans provided by non-Federal lenders to students in health professions schools. The Administration is requesting \$56.6 million to pay claims from HEAL guarantees made prior to fiscal year 1992. The fiscal year 1995 request also includes a subsidy of \$25.3 million to pay the net present value of HEAL claims arising from loans made in fiscal year 1995 and \$2.9 million for HEAL administrative costs. Finally, the request reflects a ceiling of \$375 million on HEAL loans to be insured in fiscal year 1995.

AIDS

In addition to the programs authorized under the Ryan White Care Act, the request includes \$16.4 million to continue the AIDS Education and Training Centers program and \$7 million for the AIDS Dental Reimbursement program.

CONCLUSION

We at HRSA see the coming year as one with numerous opportunities to move the public's health agenda forward. With your assistance, HRSA will continue to do more for the people who need our help.

Mr. Chairman and members of the Committee, my associates and I will be pleased to address any questions or comments you may have on the specifics of this budget request.

BIOGRAPHICAL SKETCH OF DR. CIRO V. SUMAYA

Name: **Ciro V. Sumaya, M.D., M.P.H.T.M.**

Position: Administrator, Health Resources and Services Administration, U.S. Public Health Service, Department of Health and Human Services.

Birthplace and date: Brownsville, Texas, August 1, 1941.

Education: B.A.—1962, University of Texas, Austin, TX; M.D.—1966, University of Texas Medical Branch, Galveston, TX; M.P.H.T.M.—1973, Tulane University, New Orleans, LA.

Previous positions: 1990–Present: Associate Dean for Affiliated Programs and Continuing Medical Education, University of Texas Health Science Center at San Antonio (UTHSC-San Antonio); 1987–90: Associate Dean of Continuing Medical Education, UTHSC-San Antonio; 1983–87: Professor of Pediatrics and Pathology, UTHSC-San Antonio; 1978–83: Associate Professor of Pediatrics and Pathology, UTHSC-San Antonio; Consultant, Diagnostic Virology Laboratory, Bexar County Hospital; 1976–77: Assistant Professor of Pediatrics and Pathology, University of Texas Health Science Center at San Antonio (UTHSC-San Antonio); Director, Diagnostic Virology Laboratory, Bexar County Hospital; 1973–76: Assistant Professor, Department of Pediatrics, Division of Infectious Diseases, UCLA School of Medicine, Los Angeles, CA.

Post graduate training: 1966–67: Intern, Los Angeles County General Hospital, Los Angeles, CA; 1967–69: General Medical Officer, Whiteman Air Force Base; 1969–71: Pediatric Resident, St. Christopher's Hospital for Children, Philadelphia, PA; 1971–73: Post-graduate fellow in Pediatric Infectious Diseases and Instructor, Department of Pediatrics, Tulane University School of Medicine, New Orleans, LA; Clinic Physician Tuberculosis Control, New Orleans, LA.

Organizations and memberships: 1991–present: American Academy of Pediatrics Task Force on Minority Children's Access to Pediatric Care; 1990–present: Texas Medical Association Committee on Rural Health; 1988–present: Editorial Board of Texas Medicine; 1988–present: National Action Forum on Hispanic Health; 1987–present: Texas Medical Association Subcommittee on Continuing Medical Education; 1986–89: Consultant, Pan American Health Organization for development of Hospital Infection Control Program in Santiago, Chile; 1978–84: Reviewer, Grant Proposals Kroc Foundation, Santa Ynez, California; 1976–present: Reviewer, Journal of Pediatrics, Pediatrics, American Journal of Diseases of Children, Journal of Infectious Diseases, Pediatric Infectious Disease Journal, Texas Medicine, Annals of Internal Medicine, Journal of Clinical Microbiology.

CENTERS FOR DISEASE CONTROL AND PREVENTION

STATEMENT OF DAVID SATCHER, M.D., Ph.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Next we will turn to Dr. David Satcher, Director of the Centers for Disease Control and Prevention.

Dr. Satcher.

Dr. SATCHER. Thank you, Mr. Chairman. I will be submitting my statement for the record, so I will summarize by saying that this is my 4th month as Director of the Centers for Disease Control and Prevention, after serving for approximately 11½ years as president of Meharry Medical College, and I am very pleased to be a part of the Centers for Disease Control and Prevention.

We believe that within the context of the President's budget request for \$1,983,132,000, we will continue to advance the cause of prevention in this country.

We have identified four priorities for the Centers for Disease Control and Prevention. One is to strengthen core public health functions, and we are very pleased that within the context of the Health Security Act, the President has requested support for core public health functions. We believe that our functions of surveillance and assessment, public education, and motivational or behavioral changes are critical to the progress of prevention and of health status in this country.

Our second priority is to continue to strengthen our ability to respond to urgent threats to public health. And among the urgent threats to health we include new emerging and reemerging infections. I think this past year and in 1993 we have especially noticed the importance of this priority.

For example, the emergence of the new hantavirus in the Southwestern United States, which has affected now more than 60 people, with a 60-percent death rate, was such an urgent threat. CDC's ability to respond rapidly and to identify the cause of this acute respiratory distress syndrome and also to isolate this virus from the deer mouse played a critical role in curtailing the spread of this epidemic and saved, certainly, thousands of lives.

In addition, perhaps the reemergence of tuberculosis in this country since 1985 is another good example of these urgent threats to health. For almost 30 years prior to 1985 we saw a decline in the rate of tuberculosis in this country. Since that time, TB has increased by more than 20 percent. We estimate that more than 50,000 excess occurrences are due to the fact that we did not control this infection. We believe that CDC must maintain the ability to respond to urgent threats to health.

We are pleased, by the way, that we now notice a 5-percent decline in tuberculosis this year as compared to last year, and that is encouraging. But we must continue to be vigilant.

Violence is another urgent threat to health, and I will not dwell on it but we have tried to make the point that violence and other forms of injuries represent the leading causes of years of life lost in this country. They are public health problems; they are preventable. We are working with various cities throughout the country trying to identify the major risk factors and to organize programs in those communities to help prevent violence, especially among teenagers. We believe that guns in the hands of teenagers represent as much a public health problem as the hantavirus in the deer mouse or as cholera in drinking water.

Our third priority is to develop nationwide prevention strategies. We recognize that if we can improve the physical activity of people in this country, starting with very young people, the benefits will be significant. Also, if we can continue to decrease the use of tobacco, we will save many years of potential useful life lost. Unfortunately every day in this country, 3,000 teenagers take up the habit of smoking despite the fact that in the last 30 years we have seen an overall decline from 42 percent to 25 percent. We are concerned about what is happening with teenagers, so we have to continue our work in this area. We are also concerned about nutrition, and must start good eating habits in our youth. We are developing other important nationwide prevention strategies like the immunization initiative that you have heard about and which we plan to succeed in implementing beginning this year.

The AIDS prevention marketing initiative is another example of a nationwide prevention strategy.

Finally, we believe that women's health is a very important priority for the CDC, primarily because there have been so many areas of neglect. Examples include the impact of chlamydia and gonococcal infections on infertility. We now estimate that every year in this country about 150,000 women become infertile because of our failure to detect and treat chlamydia and gonococcal infections. And so we have listed that as a priority.

We are also concerned about the impact of domestic and workplace violence on women. Homicide is now the leading cause of death for women in the workplace in this country. We believe that there are many opportunities; 46,000 women die of breast cancer a year in this country and 4,600 from cervical cancer. We are strengthening our prevention efforts in all of these areas, so we have listed women's health as a priority for CDC.

Again, we are pleased to have this opportunity to discuss this budget with you. We believe that we can continue to advance our efforts. We are asking for a \$4 million increase in tuberculosis elimination and a \$5 million increase in national occupational health and safety programs. We especially want to improve our research in the workplace in terms of being able to detect hazards earlier and detect their health impact.

PREPARED STATEMENT

And as Dr. Lee explained, while our budget shows a decrease of \$110 million in vaccine purchases, it is related to the fact that we are expecting \$424 million in entitlement funds for the purchase of vaccines. And we agree that the purchase of the vaccine is not the

only problem in immunization, but we plan to coordinate access efforts at the State and local level, as well.

Thank you very much.

Senator HARKIN. Thank you.

[The statement follows:]

STATEMENT OF DR. DAVID SATCHER

I am pleased to testify before this committee for the first time as the director of the Centers for Disease Control and Prevention (CDC). CDC is an internationally renowned agency whose achievements have dramatically improved the health of people, both in the United States and around the world. It is an organization that I am proud to lead.

CDC's vision of "Healthy People in a Healthy World—Through Prevention" is particularly timely as we as a nation strive to improve health and ensure universal access to health care for all citizens. The Administration has articulated clearly the importance of prevention in health care reform and has indicated its commitment in this budget. As the nation's prevention agency, CDC welcomes the challenge and will strive to strengthen its public health activities and to make prevention a cornerstone of the new American health care system. We fully believe that through effective prevention and health promotion efforts, we can not only add years to our lives but also add life to our years.

CDC is a dynamic agency dedicated to meeting the changing and increasingly complex public health needs of the nation. As such, CDC's priorities must evolve to meet these needs. We have identified four priorities that require the immediate attention of the agency. CDC will strive to strengthen core public health functions, enrich our capacity to respond to urgent threats to health, develop nationwide prevention strategies, and promote women's health.

To fulfill these goals, the agency will employ five strategies identified through a "strategic thinking" process. First, we will develop new partnerships with groups such as churches, school systems, and businesses as we strengthen our traditional ties with state and local public health agencies, voluntary and professional organizations, and academia. Next, CDC will seek new ways to integrate and coordinate the delivery of public health programs. Third, we are building health communication and marketing strategies into our programs, particularly those that try to prevent disease and injury by reducing harmful behaviors. Fourth, the agency will continue to conduct prevention effectiveness studies to discover activities that are both effective and efficient uses of our limited health resources. Finally, CDC is committed to ensuring diversity in our workforce so that we can effectively serve our diverse population.

STRENGTHEN CORE PUBLIC HEALTH FUNCTIONS

CDC's first priority is to strengthen core public health functions. As a public health professional, I am particularly pleased to see the increased attention being given to public health and its activities in the President's Health Security Act. Title III of the Act describes both the purposes and the functions of public health. The Act recognizes the important role that public health will play in protecting Americans against communicable diseases, chronic diseases, and environmental health hazards; identifying and controlling outbreaks of infectious diseases; informing and educating the public about important health issues; and reducing behavior-related health problems.

One of the most essential functions of public health is to collect data and monitor health. CDC professionals are currently working to develop an integrated information system for public health action. This system will use electronic technology to simplify current public health reporting requirements and provide better, more timely information for decision makers and public health officials.

Another public health function is to provide training and education to public health officials. CDC provides such training to state, local, and international officials. I recently participated in the third annual Public Health Leadership Institute for state and local health officials. This year-long scholars program provides public health officials with the knowledge and skills needed to determine local public health problems and develop locally viable efforts to address them. We also train officials in state-of-the-art methods to measure exposures to harmful chemicals, to test for causes of disease outbreaks, to assess health care needs in their communities, and to measure the extent to which those needs are being met.

ENRICH OUR CAPACITY TO RESPOND TO URGENT THREATS TO HEALTH

CDC works to enrich our capacity to respond to urgent threats to health. CDC and its partners, state and local health departments, are vigilant against emerging threats to public health. Epidemiologic investigations and laboratory work done by CDC and the state and local health departments enable us to address these problems quickly and effectively.

An example of the importance of these efforts occurred last summer when clinicians detected unusual fatal cases of adult respiratory distress syndrome (ARDS) in young adults in the southwestern United States. CDC was called in to investigate the disease in coordination with state, local, and tribal governments. Many possible causes, including infectious, noninfectious, and environmental threats, were investigated before the cause of the illness was determined. Extensive testing of specimens at CDC revealed the cause of infection to be a previously unrecognized hantavirus. The virus was found to be carried by the deer mouse, a rodent common in most of North America. Through March 2, 1994, 62 cases of hantavirus-associated illness were confirmed. (Figure 1) Nearly 60 percent of these were fatal. CDC involvement has not stopped with determination of cause. Because there is no known effective treatment, CDC has implemented public and professional educational efforts to teach people how to avoid exposure to rodents, developed rodent control strategies, expanded diagnostic capabilities, conducted national surveillance of hantavirus infection, and assessed treatments for suspected cases. New cases are being detected in other parts of the country; clearly this battle is not over yet.

Injuries, including those resulting from violence, are a major threat to the health of our nation. Every year, 150,000 people die from injuries, and violence is the plague of our times—claiming over 56,000 lives annually with devastating effects on families and communities. Those most affected by injury are children and youth, making injury the leading cause of premature death in the United States. (Figure 2) Also, each year, one in four persons suffers a nonfatal injury. Yet many of these deaths and injuries are preventable. For example, CDC is promoting the universal use of child safety seats, which saved 180 lives and prevented 70,000 injuries while saving \$221,000,000 in medical care costs in 1991. If all children aged 0–4 were buckled into child safety seats or safety belts while in moving vehicles, another 200 deaths would be prevented each year and an additional \$70,000,000 saved in medical care costs. And we are supporting 25 community violence prevention demonstration and evaluation projects in 19 states. The President's budget includes \$39,308,000 for programs to prevent unintentional injuries such as motor vehicle crashes and falls, and intentional violent injuries such as homicide and suicide, including efforts begun this fiscal year to prevent violence against women.

Tuberculosis (TB) is an urgent, reemerging health threat. After three decades of steady decline, reported cases of TB have increased in the United States by 20 percent, from a low of 22,201 cases in 1985 to a high of 26,673 cases in 1992. (Figure 3) Deterioration of the public health system, TB cases associated with HIV, TB cases in foreign-born persons, and a rise in TB transmission in hospitals, prisons, and homeless shelters all have contributed to this increase. The problem has been compounded by outbreaks of multi-drug resistant TB. In 1993, CDC greatly increased its TB prevention activities, particularly the support it provided to state and local health departments. The President's budget requests an additional \$4,000,000 to strengthen TB prevention, control, and elimination programs; expand development of outreach and screening in foreign-born persons at high risk for developing TB; and continue collaboration with international organizations to address issues associated with immigration and tuberculosis.

Injuries and TB are also examples of the threats to the health and safety of our nation's workers that challenge us. More than 50,000 workers lose their lives each year to disease and injury hazards on the job. More than 3 million Americans suffer disabling work injuries or illnesses, resulting in tens of billions of dollars in preventable health care costs. The President's budget provides a \$5,000,000 increase to expand our capacity to respond to these threats. This increase will help us continue to build state-of-the-art research activities in four critical areas: (1) developing medical tests to identify hazardous work exposures at pre-clinical stages when disease can still be prevented; (2) advancing technology for monitoring the worker's environment so that associations between the work environment and diseases can be identified and so that workers can be warned immediately of hazardous conditions; (3) designing engineering solutions for preventing work-related injuries and diseases, targeted to the needs of small businesses; and (4) improving the effectiveness, safety, and practicality of personal protective equipment, including respirators. Exemplifying one of the aims of this developing program, we are presently engineering new "roll-over protection" to protect farmers operating tractors. One in every 5,000

farmers dies each year from an injury on the farm, and the leading cause of these deaths is tractor roll-overs. We are creating a device that will make the safety equipment on tractors easier to use, thus reducing the potential for misuse that can result in fatal injuries.

Public health's ability to respond to these urgent threats depends on strategies for prevention, adequate resources, contingency planning, and trained personnel. CDC works to ensure that public health laboratories have top-quality facilities and well-trained personnel. Our global disease detection networks position us to respond to domestic and international emergencies such as unknown disease and natural and man-made disasters.

DEVELOP NATIONWIDE PREVENTION STRATEGIES

A strengthened public health system enables CDC to achieve its third priority, to develop nationwide prevention strategies. To capitalize on the long-term benefits of prevention, a number of CDC programs focus on children and youth: for example, immunization, lead poisoning prevention, school health education, deterrence of tobacco use, and HIV prevention. Improving health requires that we develop effective prevention programs and support the efforts of state and local health departments as they plan for prevention in their communities.

The President's Childhood Immunization Initiative promotes one of the most effective and efficient nationwide public health programs. For every dollar spent on diphtheria-tetanus-pertussis (DTP) vaccinations, \$6.20 is saved in health care costs, and \$30.10 is saved in total costs (when productivity and other factors are considered). For every dollar spent on childhood vaccination for measles, mumps, and rubella, \$16.30 is saved in health care costs, and \$21.30 is saved in total costs. For every dollar spent on oral polio vaccine, \$3.40 is saved in health care costs and \$6.10 is saved in total costs. This program is now well under way with goals of a 90 percent rate of coverage for all children by age two and elimination of indigenous cases of wild-virus polio, measles, rubella, congenital rubella syndrome, diphtheria, and tetanus by 1996. The President's budget requests \$464,143,000 for the immunization initiative for fiscal year 1995. These funds will be used to (1) improve the vaccine delivery infrastructure, (2) develop a national campaign of information, education, outreach, and community mobilization to reach those who might not otherwise immunize their children, (3) assess progress and evaluate effectiveness of immunization efforts, and (4) continue immunization and vaccine research.

The President's Vaccines for Children Program, that will be launched on the first day of fiscal year 1995, will use Medicaid funds to purchase vaccines for needy children. This program will ensure access to vaccines for those children who are the least likely to be immunized.

Lead poisoning is another threat to the health of our children. It is the most common environmental disease of young children, affecting millions of children in the United States and leading to slowed mental development. The President's budget provides \$34,683,000 for the support of CDC's national lead poisoning prevention program. With this money CDC will support state- and community-based health agency efforts to screen young children for lead poisoning, identify possible sources of lead exposure, and develop strategies to eliminate childhood lead poisoning. In addition, CDC will support national surveillance for lead poisoning and evaluation of prevention programs for effectiveness.

Another effective prevention program is comprehensive school health. Rigorous studies have shown that comprehensive school health education is effective in reducing the prevalence of risk behaviors among young people. Preliminary results of a recent study demonstrated that for every \$1 spent on school health education, \$14 are saved in avoided health care costs. In fiscal year 1995, CDC will support comprehensive school health programs in 11 States and school health education programs to prevent the spread of AIDS in all 50 States.

We must communicate, motivate, and activate American citizens to avoid risks to health by adopting healthier lifestyles and preventive measures. One method to promote prevention nationwide is through health communications. CDC's Office on Smoking and Health is an innovator in this field. National efforts to communicate the harmful effects of tobacco use have led to a decrease in the percentage of Americans who now smoke. However, despite these efforts, 28 percent of men and 24 percent of women still smoke, and an estimated 3,000 young people start smoking every day. (Figure 4) For the first time in its history, this year's Surgeon General's Report on the health consequences of tobacco use, *Preventing Tobacco Use Among Young People*, focused on young people and tobacco. The President's budget has recognized the importance of these efforts and provides resources for their continuation.

CDC also uses health communications to prevent the spread of HIV infection. An estimated one million Americans are infected with the virus that causes AIDS; more than 204,390 people have died from the disease. Each year an estimated 40,000 or more people become infected with HIV. AIDS cases are rising, especially among young adults aged 18 to 24, many of whom most likely acquired their infections during adolescence. There is no known cure or vaccine to prevent HIV infection; thus prevention remains our best strategy. Last fall CDC launched its Prevention Marketing Initiative. This bold new effort is designed to educate and inform young adults of the risks of HIV and the measures they can take to protect themselves, including abstinence, and for those who remain sexually active, the correct and consistent use of condoms. The President's budget provides \$543,253,000 for CDC activities directed at HIV. With these resources, CDC will (1) continue to inform and educate the public, (2) monitor the epidemic, (3) prevent risk behaviors among students, (4) prevent and reduce behaviors which transmit HIV, and (5) increase individual knowledge of HIV status and improve efforts to refer people for treatment.

These are but a few of the national prevention programs supported by CDC. We know many diseases can be prevented by adopting healthy behaviors. Other diseases may be prevented by avoiding harmful exposures and by treating individuals to prevent the spread of infectious diseases. The harmful effects of still other diseases, such as diabetes, are mitigated through early detection and treatment. The President's budget will provide support to current national programs to prevent sexually transmitted diseases, tuberculosis, lead poisoning, injuries, occupational diseases and injuries, and birth defects and developmental disabilities.

PROMOTE WOMEN'S HEALTH

While all of the activities that I have discussed include women, issues specific to women's health have not always received appropriate, special attention. For this reason, I have designated promoting women's health as a priority at CDC. CDC has identified seven priority issues of special concern for women. These include sexually transmitted diseases (STD's), HIV/AIDS, breast and cervical cancer, reproductive threats—including industrial substances and chemicals to which women may be exposed at work, tobacco use, domestic and workplace violence, and conditions associated with aging. This year, 46,000 women will die from breast cancer in the United States. An estimated 4,600 women die from cervical cancer annually. While we do not yet know how to prevent these cancers, we do know that early detection and treatment greatly improve a woman's chance of survival. In fiscal year 1995 CDC will enter the fourth year of its Breast and Cervical Cancer Early Detection and Control Program. This national program brings critical breast and cervical cancer screening services to all women, particularly women of low income, the elderly, minorities, and Native Americans. The President's budget for fiscal year 1995 will enable CDC to establish greater access to screening and follow-up services, increase education programs for women and health care providers, and improve quality assurance measures for mammography and cervical cytology. Currently 45 states participate at some level.

Another health problem threatening women is infertility and ectopic pregnancy caused by STD's. Every year, approximately 125,000 women become infertile because of STD-related pelvic infections, nearly one of every ten first pregnancies is ectopic, and ectopic pregnancy is the leading cause of pregnancy-related deaths in African-American women. A demonstration project supported by CDC, in conjunction with the Office of Population Affairs, has already decreased the prevalence of chlamydia by 50 percent in the targeted states of Alaska, Idaho, Oregon, and Washington. The President's budget includes \$8,300,000 to continue this effort to prevent infertility in women.

CONCLUSION

The ability to conduct prevention research and translate research results is vital to all of our prevention programs. Prevention research at CDC has always been linked to answering the needs of prevention programs, such as needs for improved diagnostic methods, for more effective interventions to prevent outbreaks, for evaluation of program effectiveness, including quantitative policy analysis, and for effective communication techniques. CDC has been fortunate in attracting a large cadre of superb scientists from a wide variety of disciplines, and has had the opportunity to use very diverse settings, from laboratories and health department clinics in Atlanta to villages in Alaska and Africa, for such research. Over time, the complexity and sophistication of prevention research studies undertaken by CDC has increased, requiring more resources, a more diverse work force, greater academic training, and up-to-date equipment. Despite these challenges, CDC has maintained and strengthened

ened its prevention research capacity over the years. Whether we are developing new instruments for measuring blood lead levels in children or new techniques for diagnosing viruses, CDC's research is unique because our agenda is driven by the need to implement effective prevention programs throughout this country.

CDC is committed to prevention of disease, injury, disability, and death. Mr. Chairman, with your support for the President's budget request for \$1,983,132,000 for CDC, the agency will be able to make prevention a reality for more Americans. I will be happy to answer any questions now.

BIOGRAPHICAL SKETCH OF DR. DAVID SATCHER

Date and Place of Birth: March 2, 1941, Anniston, Alabama.

Marital Status: Married with 4 children, Wife: Nola.

Education: 1970—M.D., Ph.D. (Cytogenetics), Case Western Reserve University, Cleveland, Ohio; 1963—B.S. degree, Morehouse College, Atlanta, Georgia.

Other training: 1972—Completed course in Hemoglobinopathy Detection, Center for Disease Control, Atlanta, Georgia.

Academic and professional experiences: 1993—Present—Director, Centers for Disease Control and Prevention; 1982–93—President, Meharry Medical College, Nashville, Tennessee; 1979–82—Professor and Chairman, Department of Community Medicine and Family Practice, School of Medicine, Morehouse College, Atlanta, Georgia; 1977–79—Interim Dean, Charles R. Drew Postgraduate Medical School, Los Angeles, California; 1976–79—Professor and Chairman, Department of Family Medicine, Charles R. Drew Postgraduate Medical School, Martin Luther King, Jr. General Hospital, Los Angeles, California; 1975–79—Medical Director, Second Baptist Free Clinic, Los Angeles, California; 1974–79—Director, King-Drew Sickle Cell Center, Los Angeles, California; 1975–76—Robert Wood Johnson Clinical Scholar and Senior Family Practice Resident, UCLA School of Medicine, Los Angeles, California; 1974–79—Assistant Professor of Epidemiology, School of Public Health, UCLA School of Medicine, Los Angeles, California; 1974–75—Assistant Professor and Interim Chairman, Department of Community Medicine, Charles R. Drew Postgraduate Medical School, Martin Luther King, Jr. General Hospital, Los Angeles, California; 1973–74—Associate Director, King-Drew Sickle Cell Center, Los Angeles, California; 1972–75—Director, Community Hypertension Outreach Program; Physician with Hypertension Clinic, Charles R. Drew Postgraduate Medical School, Martin Luther King, Jr. General Hospital, Los Angeles, California; 1971–72—Resident in Medicine, Strong Memorial Hospital, University of Rochester, Rochester, New York; 1970–71—Intern in Medicine/Pediatrics, Strong Memorial Hospital, Rochester, New York; 1970–71—Medical Consultant, Sickle Cell Program, Rochester, New York.

Part-time employment: 1970–72—Physician, Neighborhood Health Center, Rochester, New York; 1970–72—Physician, Migrant Health Clinic, Rochester, New York.

Board certification and fellowship: 1982—Recertified, American Board of Family Practice; 1980—Fellow, American Academy of Family Physicians; 1976—Board Certification, American Board of Family Practice.

**SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
STATEMENT OF ELAINE JOHNSON, Ph.D., ACTING ADMINISTRATOR**

BUDGET REQUEST

Senator HARKIN. Now, we will hear from Dr. Elaine Johnson, Acting Administrator for the Substance Abuse and Mental Health Services Administration.

Dr. JOHNSON. Yes; thank you, Mr. Chairman and members of the subcommittee. It is a pleasure for me to appear before you today to present the 1995 budget for the Substance Abuse and Mental Health Services Administration [SAMHSA]. As you know, SAMHSA is the Federal Agency that is primarily responsible for effective treatment and prevention programs for addictive and mental disorders, conditions that exact a very high economic and social cost from individuals citizens, as well as from the collective society.

The cost of providing prevention and treatment services are far lower than the over \$300 billion annual cost of untreated addictive and mental disorders. Effective prevention and treatment of addictive and mental disorders also reduce human suffering and benefit the public safety, productivity, and of course, our Nation's growth.

To expand the availability and accessibility of effective services to all Americans who need them, Mr. Chairman, the President's budget includes a \$2.4 billion request to SAMHSA in fiscal year 1995. Included in the request is an increase of \$284 million, which includes a \$45 million proposed transfer from ONDCP's special forfeiture fund. The result, then, is a net increase of 13 percent for the Agency, which in this difficult fiscal environment represents a measure of the importance that this administration accords addictive and mental disorders.

As Dr. Lee has already indicated, the hard core drug treatment initiative will support an increase in treatment for up to an estimated 74,000 heavy users to receive effective treatment services, services that have proven successful in both breaking the cycle of addiction and in reducing the devastating consequences of substance abuse.

SAMHSA's Center for Substance Abuse Treatment [CSAT], will redirect \$35 million from existing demonstration programs to develop and test models of service system integration for the hard core population, which traditionally has been underserved by managed health care systems. Improving our knowledge about optimal treatment methodologies will be extremely valuable under the Health Security Act.

The President's fiscal year 1995 budget maintains funding for other SAMHSA programs at the fiscal year 1994 level. Within this amount, SAMHSA has undertaken several new initiatives to materially improve our programs and services, reflecting the goals of the Vice President's National Performance Review as well as other De-

partment initiatives. For example, we propose to improve services through a consolidation of the multiple demonstration authorities that reside within SAMHSA's three centers.

By consolidating the multiple authorities into one for each center, the Agency will simplify application procedures for the States and others and improve the efficiency of the grant review process, as well.

PREPARED STATEMENT

Finally, Mr. Chairman, I would like to quickly reiterate: Addictive and mental disorders are simply too costly and the results too tragic to ignore. Effective treatment and prevention strategies for these disorders are well documented. The cost of not treating and preventing these disorders far exceeds the cost of treating them. It is my privilege today to present a SAMHSA budget that will aid substantially in the Nation's efforts to reduce the prevalence and consequences of addictive and mental disorders.

Thank you, and I will be pleased to answer questions that you may have.

Senator HARKIN. Dr. Johnson, thank you very much.

[The statement follows:]

STATEMENT OF ELAINE JOHNSON

Mr. Chairman and Members of the Subcommittee, it is a privilege to appear before you today to present the 1995 budget request for the Substance Abuse and Mental Health Services Administration (SAMHSA).

As you know, SAMHSA was established less than two years ago, pursuant to the ADAMHA Reorganization Act. SAMHSA is dedicated to the development and provision of prevention and treatment services for addictive and mental disorders as part of the network of service agencies within the Department of Health and Human Services' Public Health Service.

SAMHSA is the Federal agency with primary responsibility for providing national leadership for policy and infrastructure for the development of effective prevention and treatment. These alcohol, drug and mental health problems exact a very high economic and social cost from individual citizens and from society.

Over the past 20 years, the Nation has made considerable progress in preventing and treating substance abuse and mental illness. Yet, approximately one in five Americans is currently affected by such problems. Depression alone affects twice as many Americans during their lifetimes as are affected by coronary heart disease.

The economic costs associated with addictive and mental disorders are in excess of \$300 billion annually. But far beyond measurable economic costs, addictive disorders do immeasurable damage to the social fabric of our Nation. They contribute to the disintegration of our families, the decay of our neighborhoods and the onslaught of violence that plagues our streets. Concurrently, mental illness prevents many individuals from obtaining and maintaining employment, social well being and independence. Such disorders also tax families to their limits, contribute to the incidence of homelessness, and are frequently accompanied by co-occurring substance abuse disorders.

Fortunately, effective treatment and prevention strategies for many of these illnesses have been developed. Studies have demonstrated that the costs of prevention and treatment can be far less than the costs of untreated addictive and mental disorders.

For example, in 1990, some \$63.1 billion worth of goods and services were not produced because workers were struggling with the effects of untreated mental disorders. Depression alone costs an estimated \$44 billion each year, with employers bearing more than half this cost in employee absenteeism and reduced productivity. With treatment for mental disorders, however, work outcomes improve consistently and significantly. Treatment is successful in relieving symptoms and improving function. In fact, treatments for schizophrenia, panic disorders, bipolar disorder, obsessive compulsive disorder and major depression have documented success rates

better than those for such common somatic therapies as angioplasty and atherectomy.

Effective prevention and treatment of addictive and mental disorders also reduce human suffering and benefit public safety, productivity and growth.

To expand the availability and accessibility of effective ADM services to all Americans who need them, Mr. Chairman, the President's Budget includes \$2.4 billion for SAMHSA in fiscal year 1995. Included in the request is an increase of \$284 million, which includes a \$45 million proposed transfer from the ONDCP Special Forfeiture Fund. The result is a net increase of 13 percent for the Agency, which in this difficult fiscal environment represents a measure of the importance that this Administration accords addictive and mental disorders.

Of utmost significance is \$345 million requested for a new Hard Core Initiative. The Initiative will provide \$310 million for treatment services for chronic users through a special component within the Substance Abuse Block Grant that will be allocated to the States in the same proportion that they receive regular Block Grant funds. The other \$35 million of the Initiative is for demonstration grants related to integrating hard-core users into primary and managed health care settings. These resources will help the States to combat some of the most vexing problems associated with addictive disorders.

Violence and crime, infectious disease and other pressing social ills are inextricably linked with the use of illicit drugs. According to DOJ data, half of the individuals arrested for assault and homicide test positive for illicit drugs. One-third of the individuals in outpatient methadone treatment for heroin addiction in one study reported that in the year prior to treatment, they committed at least one predatory crime. Following outpatient treatment, the number dropped to less than 10 percent.

Grave threats to the public health, such as HIV/AIDS and multiple drug resistant tuberculosis, flourish among hard core drug users. In some segments of inner-city communities, nearly half of the injecting drug users are infected with HIV/AIDS.

The Hard Core Treatment Initiative will support an increase in treatment for up to 74,000 heavy users to receive effective treatment services—services that have proven successful in both breaking the cycle of addiction and in reducing the devastating consequences of substance abuse. There are numerous examples of treatment effectiveness. A study of heroin treatment programs judged to be effective, for example, documented that less than 20 percent of graduates were regularly using drugs even five years following treatment. One substance abuse treatment program for felony offenders, to cite another example, cut re-arrest rates by almost one half. Another treatment program for injecting drug users reduced the rate of HIV infection among participants by 75 percent. SAMHSA will provide States both technical assistance and sufficient management resources to ensure that the best treatment methodologies available are employed in treating hard core populations. The Hard Core Treatment Initiative will give States considerable latitude to use these new resources to meet local priorities for hard core drug abusers.

SAMHSA's Center for Substance Abuse Treatment (CSAT) also will redirect \$35 million from its demonstration program to develop and test models of service system integration for the hard core population, which traditionally has been under-served by managed health care systems. Improving our knowledge about optimal treatment methodologies will be extremely valuable under the Health Security Act.

The President's fiscal year 1995 budget maintains funding for most other SAMHSA programs at the fiscal year 1994 level. Within this amount, SAMHSA has undertaken several new initiatives to materially improve our programs and services, reflecting the goals of the Vice President's National Performance Review and other Department initiatives. For example, SAMHSA proposes to improve services through a consolidation of the multiple demonstration authorities that reside within SAMHSA's three Centers—the Center for Substance Abuse Treatment (CSAT), the Center for Substance Abuse Prevention (CSAP), and the Center for Mental Health Services (CMHS).

By consolidating the multiple authorities into one for each Center, the Agency will simplify application procedures for the States and others and improve the efficiency of the grant review process. We will continue to identify and support priority populations and issues within the consolidated demonstration programs of each Center.

One such priority population is women. The 1995 request includes a total of \$20.9 million to initiate or expand prevention programs specifically targeted to women. New initiatives, supported through redeployment of existing agency funding, include \$10 million to expand substance abuse prevention efforts focused on adolescent women, \$4 million to support substance abuse prevention services for women in life transitions, \$1.9 million to permit the Center for Substance Abuse Prevention's National Resource Center to reach beyond pregnant and postpartum women and address the needs of all women, \$3 million for a campaign to educate women on the

dangers of alcohol and other drug use during pregnancy, and \$2 million for health care provider training.

Children are another priority population. Of the approximately 8 million children with serious emotional disturbances who need mental health services at any given time, an estimated 80 percent do not receive the type or degree of service that they need. The new Comprehensive Community Mental Health Services for Children program within the Center for Mental Health Services encourages the development of intensive community-based services based on a multi-agency, multi-disciplinary approach involving both the public and private sector. In 1994, the program is being expanded significantly through the award of 17 new grants.

Another new initiative is the CMHS AIDS Mental Health Services Demonstration program, SAMHSA's first collaborative effort with the Health Resources and Services Administration and the National Institutes of Health. These and other programs emphasize the crucial role the Center has in translating research into effective practice and preparing mental health consumers, families, providers and State authorities to meet the challenges of providing quality care in a changing health care system.

Finally, Mr. Chairman, I would like to take one last moment to describe this Agency's role in leading the Nation in the treatment and prevention of the devastating disorders of addiction and mental illness. Today we present a budget that will enable the SAMHSA Center for Substance Abuse Treatment to expand the availability of effective treatment services for the hard core population; a budget that will continue SAMHSA's Center for Substance Abuse Prevention's efforts to empower communities so that individuals who must live in high-risk environments do not become substance abusers. Addictive and mental disorders are simply too costly and the results too tragic to ignore. Effective prevention and treatment strategies for these disorders are well documented. The economic and social impact of not treating these disorders far exceeds the costs of ADM prevention and treatment services.

Thank you and I will be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF ELAINE M. JOHNSON, PH.D.

Dr. Elaine M. Johnson is the Acting Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Public Health Service, U.S. Department of Health and Human Services. SAMHSA is responsible for supporting nation-wide programs that provide services to those individuals who suffer from, or are at risk for, mental and addictive disorders, including the homeless mentally ill; substance-using, pregnant women and their families; and youth living in high-risk environments.

Dr. Johnson's extensive and distinguished Federal career includes over 20 years in the administration of prevention, treatment, and research programs within the national alcohol, drug abuse, and mental health fields. In 1988, she was appointed Director of the Office for Substance Abuse Prevention (OSAP), with primary responsibility for administering the Nation's diverse and extensive alcohol and other drug abuse prevention programs and activities. Dr. Johnson simultaneously held the position of Associate Administrator for Prevention during this period. A major focal point for her while holding this position was the identification of strategies to address the needs of children, adolescents, and adults suffering from co-occurring ADM disorders. She also focused much attention on enhancing the translation of research findings into successful treatment and prevention applications.

Prior to becoming Director of OSAP, Dr. Johnson served as the Deputy Director of the National Institute on Drug Abuse. There she assisted in expanding research activities on cocaine and established new programs to study drug use and aspects of drug users' transmission of HIV disease.

Dr. Johnson has provided extensive consultation to major professional and national groups on alcohol and other drug abuse issues and has served as consultant to the U.S. Department of State, the U.S. Information Agency, and the Department of Defense in several countries in Europe, Latin America, Africa, and Asia.

Dr. Johnson is the recipient of numerous governmental, professional, and civic awards, including most recently the 1993 Presidential Distinguished Executive Rank Award. This award was conferred by the President of the United States upon those Senior Executive Service members who demonstrate exceptional levels of accomplishment. Among her other awards are the 1991 Presidential Meritorious Executive Rank Award (also conferred by the President of the United States); the 1990 Distinguished Service Award from the Secretary of Health and Human Services; the Outstanding Service Award from the National Association of State Alcohol and Drug

Abuse Directors; and the National Medical Association's Award for Outstanding Leadership in Improving Health Care in the Black Community.

Dr. Johnson has published various articles on alcohol and other drug abuse issues. She received her Baccalaureate degree from Morgan State University in Baltimore, Maryland, and both her Master's and Ph.D. degrees in Social Work from the University of Maryland.

HEALTH CARE FINANCING ADMINISTRATION
STATEMENT OF BRUCE C. VLADECK, ADMINISTRATOR

BUDGET REQUEST

Senator HARKIN. Now we turn to Mr. Bruce Vladeck, Administrator of the Health Care Financing Administration.

Mr. VLADECK. Thank you very much, Mr. Chairman. Good morning. I appreciate the opportunity to submit our prepared statement and I will try to summarize very briefly just a few points for you.

Our 1995 appropriations request reflects our commitment to making major improvements in the programs for which we have responsibility, while staying within the bounds of strict discretionary spending limits. Our major focus is improving service to our primary customers, the more than 65 million Medicare and Medicaid beneficiaries. In doing so, we are trying to follow the principles of successful organizations that the President described Monday at the International Economic Summit in Detroit: Commitment to quality, using the best available technology, and treating our employees as our most important asset.

In order to do this, we are developing a comprehensive strategic plan which clarifies our mission, our vision for the future, our goals, objectives, and strategies. This will permit us to focus resources in an era of continuing stringency and put our energies to our highest priority. Next year's appropriations request I expect to flow integrally from that strategic planning process.

We are working aggressively to create a total quality environment that is aimed at empowering our employees and producing continuous quality improvement. We are also fully committed to implementing the recommendations of the National Performance Review. The increased contract management authority, for example, that is called for in the Vice President's report will enable us to significantly improve contractor performance. To take advantage of technology, our request for this fiscal year emphasizes the increased use of electronic claims processing and development of the nationally uniform, more efficient medicare transaction system to replace the current crazy quilt of claims processing systems.

In Medicaid, we are working very closely with the States to encourage innovation and experimentation, both in program design and administration, as we seek to bring health care costs under control. We are proposing legislation, as the first part of health care reform, to reduce Medicare part B SMI costs by \$1.9 billion in fiscal year 1995.

Program management currently represents less than 1 percent of Medicare and Medicaid benefits. We have essentially presented you with a flat-line budget, increasing less than one-tenth of 1 percent over the 1994 appropriation. Nonetheless, we will provide \$18.2 million of that request for research and demonstration for rural

health programs, including a program of new rural health care grants to help States and providers work with their communities to develop the infrastructure for improved service delivery in a world of health care reform.

Through better targeting, increased investment in technology, and other improvements, we will increase the effectiveness of our payment safeguards in the Medicare program. We expect to increase savings by more than \$176 million from such activities, while spending slightly less. Our total return on investment for program safeguards would increase from a return of 14-to-1 to a return of 15-to-1.

Our direct administrative costs represent just 16 percent of our program management costs. We are requesting additional funds for relocating our headquarters to a single site in Woodlawn, from the 11 buildings currently occupied, as well as for data processing, modeling and forecasting health care expenditures, and supporting health care reform initiatives. The request reflects a staffing reduction of 57 full-time equivalents, consistent with the President's Executive order.

PREPARED STATEMENT

In summary, Mr. Chairman, we believe that HCFA is demonstrating that a public agency administering public programs can handle national health benefit programs with increasing efficiency, productivity, and improved service to our customers by innovation in management, by the judicious use of technology through commitment to quality, and through the empowerment of our employees.

I will be glad to answer any questions you might have.

[The statement follows:]

STATEMENT OF BRUCE C. VLADECK

Mr. Chairman and Members of the Subcommittee, I am honored to be here today to present the fiscal year 1995 budget request of the Health Care Financing Administration (HCFA). Standing at the crossroads of American health care reform during the past year has made it a truly exciting and challenging time to serve as HCFA Administrator.

As we look to the future of American health care, nothing is clearer than the need for change. We at HCFA are proud to have worked with the Administration's health care reform task force to develop the President's Health Security Act. We are continuing to prepare for health care reform. We are dedicated to working with providers of health care services, States that administer the Medicaid program, Peer Review Organizations, and our other partners to serve beneficiaries better. We are focusing on improving program administration, increasing operational efficiency and productivity, building HCFA teamwork, developing agency strategic planning, fostering employee empowerment, implementing continuous quality improvement, and achieving diversity.

Our fiscal year 1995 budget request reflects HCFA's commitment to the President's mandate for change. I would like to highlight briefly three of the accounts under the jurisdiction of this Subcommittee: Grants to States for Medicaid; Payments to Health Care Trust Funds; and HCFA Program Management.

Grants to States for Medicaid.—In fiscal year 1995 the Medicaid program will serve over 36 million eligible citizens—an increase of more than 4 percent over fiscal year 1994. Federal Medicaid obligations for fiscal year 1995 are estimated to be \$96.4 billion, an increase of almost 11 percent, or \$9.2 billion over fiscal year 1994. Total Federal and State Medicaid expenditures are projected to reach \$169.1 billion in fiscal year 1995, of which the Federal share is 57 percent. We are pleased that these increases in spending are smaller than in recent years, but we will continue to work with the States to encourage innovation and experimentation to reduce further rising health care costs.

Under current law, our fiscal year 1995 Medicaid budget request is \$89.2 billion. This request is equal to anticipated fiscal year 1995 obligations less funds carried over from fiscal year 1994. Our fiscal year 1995 legislative package includes an estimated \$15 million in savings for the Federal share of Medicaid. These savings to the Medicaid program are a result of interactions with Medicare provisions contained in the Health Security Act.

Payments to Health Care Trust Funds.—Benefit expenditures under the Supplementary Medical Insurance program (SMI, or Medicare Part B) will grow 13.4 percent from fiscal year 1994 to fiscal year 1995, from \$56.8 billion to \$64.4 billion. While, as in Medicaid, this growth rate is less than that for many recent years, it still reflects the unacceptably high rates of increase in health care costs which make health care reform essential to the future of this country. Our legislative proposals take the first steps toward reform by calling for changes saving \$1.9 billion in SMI.

Our current law fiscal year 1995 request for the Federal general revenue subsidy to the SMI Trust Fund is \$37 billion—a decrease of \$8.5 billion from the fiscal year 1994 appropriation. The reason for this seeming anomaly is that beneficiary premiums—which were set in law by OBRA 1990—have increased faster than program costs, making the beneficiary share of program outlays rise. Program costs for Part B have not grown as rapidly as expected when the premium amounts were set in OBRA 1990, primarily because expenditures for physician services have grown more slowly than projected at that time.

Program Management.—Our Program Management request shows that it is possible for a government agency to handle national health benefit programs with increasing efficiency and productivity. We are actually requesting less than a 1 tenth of 1 percent increase in our Program Management funding: Our fiscal year 1995 Program Management current law estimate is \$2.2 billion—an increase of \$1.7 million above the fiscal year 1994 appropriation.

Research and Demonstrations.—The fiscal year 1995 Research and Demonstrations request is \$68.6 million, \$17.4 million less than our fiscal year 1994 appropriated level. Consistent with the Administration's emphasis on investment in rural initiatives, our fiscal year 1995 Research request includes a total of \$18.2 million for 3 rural health programs: \$7 million for the Rural Health Care Transition Grant program; \$3.5 million for the Essential Access Community Hospital/Rural Primary Care Hospital Grant program; and, \$7.7 million for New Rural Health Grants. In addition, we request \$4.5 million to continue the Health Insurance Information, Counseling, and Assistance Grants program with a managed care emphasis. We have also moved the Medicare Current Beneficiary Survey (MCBS) from the HCFA Administrative Costs Account to Research since that data base is key for research essential to Health Care Reform and HCFA researchers will use MCBS data in various studies of health care financing and health care reform.

The remaining \$36 million includes \$22.3 million for the continuation of ongoing research activities and \$13.7 million for the implementation of new projects that support Congressional and Administration priorities. We estimate that \$12.4 million will be spent on new starts and continuation projects that are Congressionally mandated.

Medicare Contractors.—Our request for Medicare Contractors demonstrates that we continue to strive to do more with less while emphasizing customer service. In fiscal year 1995 Medicare Contractors will process an estimated 785 million claims—a 5 percent increase over fiscal year 1994. Despite this growth in volume, our Medicare Contractors request—\$1.61 billion—contains a very small decrease of less than one percent, or \$5 million, below the fiscal year 1994 appropriated level. We have not requested Contractor contingency funding for fiscal year 1995.

Contractor functions are at the heart of the Medicare program. Thus, the majority of our efforts to contain costs and increase administrative efficiency have focused on this Program Management activity. In the past few years, we have made great strides in the areas of Claims Processing, Payment Safeguards, and Productivity Investments and we will continue to do so.

Of our fiscal year 1995 request, \$1.2 billion, or 72.2 percent, will support Claims Processing activities. To promote greater efficiency and uniformity, we are developing a standardized Medicare Transaction System to replace the variety of current contractor claims processing and payment systems. This will not only be more efficient but will facilitate implementation of future legislative changes. In fiscal year 1995 we will continue to encourage the use of electronic media claims (EMC). Fiscal year 1995 will also see the first full year of operation of four specialized durable medical equipment contractors, which will improve both efficiency and service to beneficiaries. Within Payment Safeguards, contractors will concentrate on cost-effective activities and efforts to improve program integrity. Thus, while spending for

Payment Safeguard activities will go down slightly by \$7.2 million, savings will go up by \$176.3 million.

Medicare State Certification.—The Medicare State Certification program ensures that facilities participating in Medicare meet Federal health, safety, and program standards. The Medicaid Survey and Certification counterpart is funded through Grants to States for Medicaid. State Survey and Certification activities seek to secure quality services for all Medicare and Medicaid beneficiaries.

The fiscal year 1995 Medicare State Certification budget request is \$145.8 million—the same as the fiscal year 1994 appropriated level. The request will support inspections of all nursing homes and home health agencies, which are statutorily mandated, as well as inspections of a minimum of 10 percent of non-statutorily mandated facilities. In addition, HCFA will continue to pursue increased program efficiencies and look at ways to optimize our survey process.

Clinical Laboratory Improvement Amendments (CLIA).—The CLIA program involves inspections of laboratories, including those in physicians' offices. This program is designed to enhance the quality of tests and test results for all Americans—not just Medicare and Medicaid beneficiaries.

The CLIA program is funded entirely through user fees credited to this appropriation. Therefore, we are not requesting additional appropriated funds for this program in fiscal year 1995. The current fiscal year 1995 estimated program level is \$50.6 million—an increase of 12.3 percent over fiscal year 1994.

Administrative Costs.—The Administrative Costs portion of the Program Management account supports the day-to-day operations of HCFA. Our fiscal year 1995 request of \$367.1 million includes a request for \$15.2 million to fund our agency headquarters relocation. The General Services Administration is proceeding with construction on the government-owned property. The new HCFA headquarters is a key to our long-term productivity. Currently, HCFA Woodlawn staff are scattered among 11 buildings. Consolidation of these employees in a single site will streamline our operations, greatly enhancing our administrative efficiency.

President Clinton has directed all Federal agencies to reduce their staffing levels. In fiscal year 1994 we will reduce our workforce by 50 full-time-equivalent (FTE) employees. Our fiscal year 1995 request reflects an additional reduction of 57 FTE's.

Key to our strategy to do more with less are recommendations of Vice President Gore's National Performance Review together with our Total Quality Environment (TQE) initiative. We will streamline our administrative processes and foster continuous improvement in the quality of our services. Cultivating the talent of HCFA staff will increase our ability to meet the future challenges in the Medicare and Medicaid programs. Our TQE initiative will continue to develop a management style of inclusion. By involving HCFA employees in all aspects of the decision-making process, we will be better able to face the challenges of health care reform in the future.

Conclusion.—Our fiscal year 1995 budget request comes at a very exciting time in American health care, as health care reform is at the top of the national agenda. Enactment of health care reform will ultimately decrease the rate of increase in Medicare funding because of national health care cost containment with Medicare no longer sharing in the cost of uncovered care. Our fiscal year 1995 request was formulated with the impending reforms in mind and it is both flexible and constrained. I am confident that this budget request will enable us to respond quickly and effectively to America's call for change.

Thank you for the opportunity to present HCFA's budget request. I look forward to working with this committee and I would be happy to respond to any questions or suggestions that you may have.

BIOGRAPHICAL SKETCH OF BRUCE C. VLADECK

Bruce C. Vladeck was sworn in as administrator of the Health Care Financing Administration on May 26, 1993. He was nominated by President Clinton March 5, 1993, and confirmed by the Senate May 24.

As HCFA administrator, Vladeck directs the Medicare and Medicaid programs, which help pay the medical bills of 67 million Americans at a projected cost of almost \$230 billion in fiscal year 1993. Vladeck also serves as a key health policy advisor to the HHS secretary and other top administration officials.

Vladeck came to HCFA from the United Hospital Fund of New York in New York City, where he had been president since 1983. He directed the fund's involvement in grantmaking, health services, research and policy development in New York City's health care. Vladeck also was a member of the Prospective Payment Assess-

ment Commission, the New York State Council on Health Care Financing and the New York State AIDS Advisory Council.

Prior to joining the United Hospital Fund, Vladeck was assistant vice president of the Robert Wood Johnson Foundation in Princeton, N.J., during 1982-83. He served as New Jersey's assistant commissioner for health planning and resources from 1979-82. From 1974-79, Vladeck taught public health and political science at Columbia University.

Vladeck was a director of the New York City Health and Hospitals Corp. and a trustee of the Henry J. Kaiser Family Foundation. He also served as a member of the Institute of Medicine, National Academy of Sciences, where he chaired the committee on health care for homeless people.

Vladeck received a bachelor's degree from Harvard University in 1970. He received a master's degree in 1972 and a Ph.D. in political science in 1973, both from the University of Michigan.

He is the author of "Unloving Care: The Nursing Home Tragedy," published in 1981, and of many articles and book chapters on various subjects.

Vladeck was born in New York City on Sept. 13, 1949. He is married to the former Fredda Wellin of Detroit, Mich., and they have three children.

PUBLIC HEALTH INITIATIVE IN HSA

Senator HARKIN. Mr. Vladeck, thank you very much for your statement. I did not introduce Mr. Bill Beldon, and you are the Budget Officer for the Department. Thank you for being here.

Dr. Lee, let me kind of cover something that I was anticipating covering with Secretary Shalala, but in the interest of time and our votes I let her go without staying here through that period of voting that we had. Regarding the testimony that the Secretary offered in referring to your area on the public health initiative and the President's Health Security Act—there is \$1.1 billion in there which includes increases for the National Institute of Health, community and migrant health centers, and other programs for urban and rural America.

This initiative in the Health Security Act is designed to build service capacity and increase access to health services as health insurance becomes available. Obviously, what good is health insurance if you do not have access and availability.

It is my understanding that for the next year the public health initiatives are fully funded within the pay-as-you-go requirements of the Budget Enforcement Act, but from 1996 through 1998 these initiatives are assumed to be funded within the discretionary spending caps.

Well, during that period of time, as you can see from our chart over on my far right, Dr. Lee, going out to 1998 we are still under that hard freeze and under those caps, and we will be very tight. And you see the green line is the baseline. So I firmly believe if we are going to have these new initiatives succeed they must have new funding as provided in the Health Security Act, and it must be some form of mandatory funding outside the discretionary budget caps or we are never going to get there.

I honestly do not know where the funding would come from, and I guess I am just asking you, Dr. Lee, since most of this is under your bailiwick, if you have any thoughts on this and how we find the proper mechanisms or where this funding is going to come from. I mean, I am on your side on this. I am just trying to figure out what we can do, and I do not have a specific hard question about where, but just your thoughts on it.

Dr. LEE. Mr. Chairman, the administration is clearly committed to working with the Congress and the leadership to identify how this can be accomplished. As you pointed out, in the fiscal year 1995 budget it is under the pay-as-you-go provision, and that would require, of course, enactment of a revenue source or identification of a revenue source. We will be working very closely with you and with the other leaders in the Congress to identify those sources.

As you point out, currently the public health initiative is under the discretionary cap. But we are committed to working with the Congress to find the funds necessary for these programs from 1996 through 1998, and I believe that will be accomplished. We are very optimistic.

It is going to take a little while to figure out the best way to do that. And clearly, it is going to require the judgment of congressional leadership to help us accomplish that.

Senator HARKIN. Well absolutely, Dr. Lee, and I asked that question and solicited a response again to point out the need to move the health care reform package through the Congress this year. If we do not, God forbid. That is what we are facing next year. We need a comprehensive health care reform bill with its own funding sources so that we can cover these items, which we do under the broad sort of umbrella of health care itself rather than dumping it all just on this subcommittee to try to find funds when we simply do not have the resources within the discretionary outlays we are going to have next year.

So again, I make that point to reaffirm what you and the administration are working for, and that is to get a health care reform bill through this year. We have to have it or we are going to be in very deep trouble.

Dr. LEE. We certainly agree with you, Mr. Chairman.

Senator HARKIN. Thank you. I thought you might. [Laughter.]

PHS PRIORITIES

Dr. Lee, you have been Assistant Secretary of Health for about 1½ years. As you indicated, you had been there before. What have you determined are the greatest needs or priorities for public health agencies? Can you give me some priority listing, what are the greatest needs that we ought to be focusing on?

Dr. LEE. Yes; if we look, Mr. Chairman, at our goals, which are to improve the health of the American people, that is really the goal of the Public Health Service and the goal of the Department with respect to health, and we have that as an overall goal.

We also have a goal to reduce the disparities in health status of those individuals in the population whose health status is lower than the rest of the population in the United States; for example, Alaska natives or American Indians. And there are other socioeconomically disadvantaged groups whose health status is less than the rest of us.

The third is to achieve the goal of implementing clinical preventive services widely.

Achieving the health care reform objectives in the Health Security Act has been a major priority for us during the past year. We developed the title III public health initiatives included in that Health Security Act to achieve those objectives through both a re-

form of the personal health care system and revitalization of the public health system.

Our second priority area is research, and there are three agencies principally engaged in research: The National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Health Care Policy and Research. The fundamental research at NIH is really the foundation for all the progress that we can make. It is biomedical research; and there is also behavioral and some social science research that is part of the overall effort.

The third priority, and again this fits in with the health care reform legislation, is prevention. Dr. Satcher has very eloquently described some of the priorities there: Strengthening core public health—that may not sound very sexy, but that has to do with preventing communicable disease, preventing and reducing cigarette smoking, and several other initiatives. This has to be one of our highest priority areas.

CDC will be hosting a program with the Surgeon General and Dr. Satcher in the lead later this month, with 500 satellite linkups. We expect 15,000 people participating from around the country, in a 2 hour dialog with Dr. Satcher and Dr. Elders to talk about how to implement the recommendations for community based initiatives on smoking. CDC has just issued the guidelines to schools to prevent nicotine addiction, to create smoke-free environments in the schools, and to create programs for smoking cessation for both teachers and students who are addicted to nicotine.

There is close cooperation between my office and CDC to facilitate these programs. CDC has provided the leadership for the development of 50 State programs for tobacco control. They began to take off a couple of years ago, and CDC has been playing the major role. An initiative at the National Cancer Institute is also funding some of these programs. We now have programs in 50 States for tobacco control. Those are some of the kinds of prevention initiatives. Dr. Satcher has mentioned others.

And of course, one of the highest priorities this year and for the next 2 years certainly will be immunization, and the leadership that Dr. Satcher has shown in putting that program together and moving it forward. We are very optimistic that we will be able to achieve our goals, and that is very important.

The fourth area is in HIV and AIDS, including research, prevention, and treatment, and that is reflected in the budget.

The fifth area is in substance abuse and the efforts now being made. Dr. Elaine Johnson has described those efforts with the increased funding for hardcore drug and substance abusers in the proposed budget.

Finally, through the recruitment efforts, with new leadership at NIH, CDC, HRSA, and with Dr. Johnson's very strong leadership in SAMHSA, we feel that leadership in this area of public health is another vital role that we play in the Public Health Service.

That basically would summarize the priorities as I see them. I must say I am more optimistic. I think we see a lot in the media about health care reform not moving forward. I feel quite the contrary. I think there is very strong leadership in the Congress. Certainly the President and the First Lady have made the priority clear in terms of the Health Security Act, and I feel quite optimis-

tic that we will achieve a historic goal in terms of health care reform before this year is out.

Senator HARKIN. Thank you very much, Dr. Lee. I will now turn to Senator Stevens. I have a question, though, about the whole vaccine program and how it is going to be administered. I will get to that as soon as Senator Stevens finishes his questioning.

Senator Stevens.

OPENING REMARKS OF SENATOR STEVENS

Senator STEVENS. Well, thank you very much, Mr. Chairman. I have submitted 10 questions for the record. I want to highlight a couple of them. Let me say to you and the panel here that I think there is a general agreement that we need health care reform. I, today, have not found the answers in the bills that are being considered to the questions pertaining to the federally financed programs: Veterans Administration, Indian Health Service, the CHAMPUS Program for military dependents, FEHB, Medicare, the DOD uniformed personnel, the DOD retired personnel.

All of those people are direct beneficiaries of existing Federal programs that, if I understand the budget, are currently frozen, and yet the needs are expanding and the concepts that are involved in those programs cannot be met with insurance policies or vouchers. They are entitlements that unless we change the basic entitlement law will continue on into the future, and I would hope that we will see something before we are through that deals with them.

I have to tell you, the bill that I cosponsored, Mr. Chairman, the Chafee bill, deals with them by saying they are set aside, they will continue to be funded until this new system is up and running and they can be worked into the program. Particularly the Veteran's program is very difficult, and the President's program is an interesting one but of course will open the veterans hospitals to the families of veterans. But I do not know of any pediatric wards or OB wards in veterans hospitals. As a matter of fact, I do not know of many veterans hospitals that do not have an overwhelming demand for service right now and cannot meet that demand.

So I do think we have got a lot of work to do and we have got to agree what we must put aside if we are going to get this bill through this year. And I am more than willing—many of us are—to work with the majority to see to it we get a bill, but we have got to get some basic understanding as to what is going to happen to DOD retirees, for instance. Now, those people that are fully retired are entitled to medical service for the rest of their life. I do not think you fulfill that by just giving them an insurance policy, particularly one that has limited benefits. They do not have any limits on their benefits today, and there are some commitments out there that we have made in the past that must be kept.

Let me turn to my questions, and I am grateful to CDC because of these charts that I am going to pass on to the chairman. So I hope he will see them. And this is the chart of occupational fatality rate comparing Alaska to the United States, Finland, Norway, Denmark, and Sweden. We are going off the wall. The chart is not big enough.

Here are fatalities by occupation in Alaska, and the blue line is the one that is going off the wall. It just so happens that is fisher-

men, and having one son who is the captain of a fishing boat means I keep very close tabs on those statistics.

So what I am really getting to is that there seems to be a decision, a preliminary decision—I hope it is preliminary—that the NIOSH unit that we worked so hard to get to Alaska may leave Alaska. It is a very small unit, it does not cost much money, but I have got to tell you it has already had an impact. And it is the kind of a unit that I think, given these statistics, the return for the investment in that small unit dealing with the establishment of new concepts, for instance just in terms of the personal flotation device which was really very much explained and brought into the Alaska scene by NIOSH, that the difference those people had, that personal flotation device, more than one-half of them survive, whereas if you do not have it about one-seventh of them survive.

Now, NIOSH is absolutely necessary, I think, to deal with the Alaska scene. It is a violent scene, it is a scene where we do not have many roads, we travel by air, we have the highest fatalities by air. But if you look at it, the reason is that the demand for transportation in an area one-fifth the size of the United States only by air primarily in the wintertime is very dangerous. Our fishing vessels fishing out there on the high seas, they fish primarily in December, January, and February, and I have got some photographs. I have got even more than that. I have got a video I can show you. If you do not get seasick just watching it, you are a fisherman, you know?

But my plea to you is that when you review my question about NIOSH is to really go back and take a look at it. I know that it is a different expense and I know there are demands on you from the point of view of full-time employees, but I just pray you are not going to take that NIOSH unit out of Alaska. It is doing a good job and has contributed substantially to the concepts of sound change. And some of the people in those industries have been after me tooth and nail because of some of the things that we want to require them to do in order to prevent those accidents. And I would urge you to, notwithstanding that, to keep that pressure on. We need that pressure.

So I am not asking you for an answer to that. I would ask you though, right now, before 5 weeks out a laminectomy that dealt with spinal stenosis with a rather severe compression, and I was very—being a Senator, being in the hospital, you have been there, everybody came in to see me, right? They all came in to see me about the same thing, and that is they say that the Agency for Health Care Policy and Research Back Pain Outcomes Assessment Team, that the work that was to be done was funded by that unit, AHCPR, but it was a sole-source contract with a concept of evaluation of the basic process or procedure of back surgery being one that is not favored by the contractor.

I do not know if any of you have ever had back pain, but I have got to tell you, they tell me the only thing next to it, ladies, is delivery, right? But it is something that every man ought to have, then, because we would understand you all a lot better. But that is the worst thing I ever faced in my whole life, and I come up and the surgeons are telling me do you realize that the unit you helped finance has turned over the study of the methodology of that basic

type of surgery to a contractor that was on record opposing that kind of surgery to begin with?

Now, who am I talking about? Who oversees the Agency for Health Care Policy and Research?

Dr. LEE. Well, I do, Senator Stevens. The Administrator of the Agency reports to me. And we will get the detailed information on that particular activity. I think you are referring to the development of the practice guidelines, and what we do is contract out because those are non-Federal individuals who develop those practice guidelines. We have recently issued guidelines on cancer pain. We issued earlier guidelines on the treatment of depression in primary care. And I will check on the status of the development of that particular guideline and see where we are with it because I do not have detailed information. But we will get that information for you as well as the nature of that particular contract and the contractor.

Senator STEVENS. Well, I think the good Lord is sending the Senate a message. Senator Dole and I both had prostate surgery, too, and I read an interesting article the other day from the medical profession saying maybe prostate surgery is an unnecessary procedure also. Now, I really hope that we are not going to give the study to the people who review the question of whether we should pursue that in terms—I think it is whether we should pursue it in the new program, which would be one of the benefits that would be insured, right? That is the ultimate goal.

Dr. LEE. There certainly are indications for prostate surgery of various kinds, depending upon the condition. There are also new modes of treatment being developed that may make medically treatable what required surgery for some patients in the past. We have recently issued practice guidelines under the leadership of urologists in the development of those guidelines. Again, not Federal guidelines, but we facilitate that process, and we would be glad to make those available to you.

Senator STEVENS. Well, I read them. And so does Senator Dole.

Dr. LEE. I read them also.

Senator STEVENS. This deals with trying to pass out information to men about prostate problems, but my point in mentioning in this connection is would you give a contract to a group of doctors to analyze the necessity, and even more than that, whether or not prostate surgery is going to be included in the new National Medical Plan?

Dr. LEE. Prostate surgery is definitely included in the plan. It is part of the benefit. It is a medically necessary and appropriate procedure, and it would be included in the plan. And that, of course, is determined by the physician and the patient.

Senator STEVENS. I have not made my point, Dr. Lee. My point is you are not going to give that study about prostate surgery being included in the benefit plan to people that opposed it. So why give the pack pain study to people who oppose surgery for back pain?

Dr. LEE. Well, I will have to get that information, Senator Stevens, because I do not have the details on that individual contract. We did have the guideline on treatment of prostate recently released. But I will certainly get the information for you on the guideline on low back problems.

Senator STEVENS. Well, I want to tell you, having gone through that, I think your profession probably is better than any profession I know. If we had three sets of doctors that told us what our options were, do nothing, have conservative treatment, or surgery, you cannot get better service than that from any profession that I know of. And so I am not complaining about prostate surgery. I am trying to make the point that I do not think that the back pain surgery ought to be turned over who does not believe in that surgery.

And incidentally, in the process of getting opinions I bumped into people in your profession who do not believe you should have basic operations for back pain. It is possible to work it out conservatively over a period of time.

Dr. LEE. Well, that is true for some conditions, but for other conditions like spinal stenosis, for example, and particularly if there has been some nerve damage, and of course, with very severe pain it is very appropriate. The back is subject to many different problems. But in terms of some of those, surgery is absolutely indicated.

Senator STEVENS. I do have a question in the record for that, and I am not belaboring it. But I hope that your people will take a look at that issue.

Dr. LEE. We certainly will.

Senator STEVENS. Let me ask you, and I do this as you know, quite often, how many of you have been to Alaska? [Show of hands.]

Good. Now, there are some people who have not, and I would like to talk to them about when we are going up, and I would hope that particularly—

Senator HARKIN. In the summertime. [Laughter.]

Senator STEVENS. Well, our best friends visit us in the wintertime, you know, because they see how we live most of the year. [Laughter.]

Dr. Satcher, I know you are involved particularly in your CDC effort and you have been very cooperative, your people have, in terms of dealing with our problems in Fairbanks, in particular with regard to the air quality problem and our use of the substances in our gasoline. And I would hope that you will come back and visit us again and see how we are doing in that regard. It does seem to be a great problem for us.

We have about, what, 9 hours a year that we are out of sync as far as clean air standards in a State that prides itself on its clean air. But because of temperature inversions we get those in the wintertime when there is a nice fog blanket over the cities, and then we have to buy fuel that is imported from Canada for 5 or 6 months, for a concept of about 8 hours that a deviation from the national standards.

I think sometimes we ought to change the national standards, but at least I think we ought to get people who visit us and understand the problems in the wintertime. And your two young doctors who came up and worked with us did a very good job on that.

Dr. LEE. Senator Stevens, I should say that I will be visiting. I had a recent meeting in Vancouver, WA, with over 200 American Indian tribes and Alaska Native tribes and heard detailed descriptions of the situation in respect to the Alaska Natives. I am plan-

ning to visit, to look into those conditions and also, of course, work with people at the State level to look at the other conditions.

But going back to your comments about the Health Security Act, the reforms and the Indian Health Service, the purpose of this consultation and others, is to basically consult with all the tribes in the United States and all the Alaska Native tribes, and I must say I was very impressed with what has been accomplished to date in Alaska despite the severe limitations of resources. We do plan to visit, and we will be working with the tribes to really determine what needs to be done in terms of the Health Security Act to make it work for the tribes to achieve the objectives that we all have and to meet the treaty obligations that we have with respect to those tribes.

Senator STEVENS. I believe in Alaska, if you are a member of the Indian Health Service or the Coast Guard that is all you need to say, we have such deep respect for the people that serve in those two organizations.

I hope you will come to the villages.

Dr. LEE. Absolutely. We plan to.

Senator STEVENS. You know, years ago we started from this table, one like this, the concept of the community health aids in Alaska, and those young women—normally young women—have probably at most a high school education. They are the contact for the people in a small village with the outside world, as far as health care is concerned. They have improved. We are talking to the Mayo people about trying to see if we can upgrade their training by sending some of our people down. As you know, your people are working with ours to help see if we can do that to get them training in clinics and rural areas in the Northwest.

But I saw something the other day. We saw one of your—you were here. It is your demonstration of the ultrasound, computerized ultrasound. Did you see that? We had a demonstration of the computerized equipment that is available to have ultrasound from Montana into Rochester where there was a doctor that looked at it. It was a nurse practitioner giving the ultrasound. A woman had a potential problem, a breast problem. There was a doctor in Rochester and a second opinion doctor in Florida looking, giving instructions to that nurse practitioner.

Since that time, I have seen a unit which is an operating unit with a pair of hands that are hanging over a table, and the doctor very far away puts his hands into a similar pair of gloves and picks up instruments and the automatic hands pick up the instruments and make an incision. We can literally have remote assistance for minor surgery in terms through—again, through telecommunications. I hope that we get there some day with Alaska, but it is going to be very expensive and it is going to take some time.

Right now I would like to urge you to come take a look at what is going on now in those community health clinics. They are doing the best they can, and I understand you are doing the best you can with the limitations on financing. But you should see them.

Dr. LEE. I agree with that, Senator. We had a presentation by several of the community health aids at this meeting in Vancouver, WA. They are doing a phenomenal job. One of my former fellows

worked at Kutzaboo, and was linked by radio to community health agents and villages in that region.

We are also working with the Advanced Research Projects Agency in the Defense Department to explore the telecommunications capabilities and possibilities with respect to linking Alaska with Tripler, for example, in Hawaii. I think there are some very important opportunities, and those are two areas that we are exploring actively.

Senator STEVENS. I appreciate it, but I would urge you to come and take a look now because the weak link in the community health aid concept is, in fact, the health aid, now. The educational attainment of those people is limited. We have to have some funding to give them computer training to take them to where they see and operate some of those things.

Today, it is not possible for us to move this new technology into those community health aid stations without replacing the community health aid. That is not going to work. It is generational. We have to upgrade the education for those people so they can provide the functions that may be available under this new National Health Care Plan. But it is not going to work just by saying it is available.

Dr. LEE. We agree with that.

Senator STEVENS. There are a lot of things that have to be done, and I think only someone with your background and others who work with you going out into the bush and seeing those. The ones you are hearing about around Kutzaboo are model stations. They are all within flying distance of an Indian Health Service hospital.

Go to Atka. In order to get from Atka to Anchorage, you have to go to Adak. There is no way to get literally from Atka to Anchorage. You have to go to Adak, which is going southwest first, and then you fly in 2,000 miles to Anchorage, and the Indian Health Service is in Anchorage. And you provide Indian Health Service treatment. But who pays the bill from Atka to Adak and Adak to Anchorage?

And if it is a medivac how does it come about, and if you cannot evacuate them how does that community health aid in Atka help that patient survive until they can medivac them? I mean, the problems that are developing now because of the rush of modernization are almost worse than what we had that brought about the establishment of the very, really at the time, crude assistance.

I will quit by saying to you that it was another fellow named Lee over at the Department of Interior who was an Assistant Secretary of Interior who was in the BIA at the time who helped us establish the community health aids, really, when before statehood the schools were run by the BIA in Alaska. As the State took over those schools we lost the superintendent who had the radio in each village and had a wife who was usually a nurse. They soon became nurses anyway. And they provided the care for the native people in these villages using that connection, the radio, into the Anchorage hospital.

Now, that has been replaced by the community health aid. They can no longer rely just on radio any more. We must go to telecommunications, and that is what I would urge you to come see and see the demand that is opening up. And it is a very costly de-

mand. We have got to find ways to meet it within the budget that is available here. But it is going to be a very difficult problem.

Dr. LEE. Thank you, Senator.

Senator STEVENS. I appreciate your answers in response to my questions. But my basic plea to you right now is, and the reason I am here this morning taking the time, do not take the NIOSH unit out of Anchorage, out of Alaska. We need that more than I think anything else right now.

And Dr. Satcher, I appreciate your position on that. I know that you are going to have to work to scramble to find some money. But maybe my friend and I can scrape a little bit off here and there and make sure you have money to keep that up there. It is not that costly, but it is doing wonderful work, and it has just got to stay in Alaska.

Thank you.

Senator HARKIN. Thank you, and I can assure you, Senator Stevens, we will work with you on that. Obviously, the need is there, and we will work with you on it.

Senator STEVENS. Every time I hear a broadcast about another boat that has gone down out there along the ice pack I scramble to the phone to find out where my son is, and now we do have telephone connections to those boats so we can find out immediately. But it is a very worrisome thing for those of us who have young people, and almost every family in Alaska has someone on a fishing boat. It is the largest employer in the State of Alaska, the fishing industry.

Thank you.

Senator HARKIN. Dr. Lee, just one more question for you. Then I have a couple for some of the other people who are here. This has to do with the Vaccines for Children Program that will be coming under your jurisdiction. And I was just in Iowa last week and heard about this. I was at a community health center. And evidently only federally qualified health centers are eligible to receive assistance for vaccines for those children whose health insurance does not include coverage for immunization.

In Iowa, we have only three federally qualified health centers, so it is a rural State, our programs are run through the county health boards, the county health departments, which by definition are excluded from the program.

I had written a letter to Secretary Shalala on March 7 asking that she designate State and county health departments as federally qualified health centers for the purposes of Vaccine for Children Program, because, obviously if we do not in rural areas like Iowa, I do not know how we are going to get to these kids. If there is some way we can work this out, I sure hope we can.

Dr. LEE. We are looking at that, Senator Harkin, and preliminary information from the General Counsel's Office would suggest that the Secretary cannot waive it. So we are looking to see if there is a way to delegate the authority from the existing centers, and if not we may come back to you and ask for authority to actually designate the State and local health departments directly, and also the private physicians, of course, who are important in Iowa, as well as others. But we are working very hard to resolve that problem, and appreciate the fact that you brought it to our attention.

Senator STEVENS. Well, I look forward to hearing from you on that.

Dr. SATCHER. I agree. It is something that we are looking at. We have been working very closely with the State and local health departments, as well as with the private sector. So we hope that that can be done, but we are going to find a strategy to solve this problem.

Senator HARKIN. Well, let me know as soon as possible if we need to do anything here.

Dr. LEE. We absolutely will.

Senator HARKIN. To have to delegate it out, that would be the quickest and best resolution of the whole thing.

Dr. LEE. We will look at that, and we are going to determine that very soon and we will let you know.

Senator HARKIN. Thanks very much.

Dr. Sumaya, in HRSA the administration has proposed the consolidation of over 25 categorical health profession programs into five consolidated grant programs, but have requested overall funding be reduced by \$15 million. So it is the old thing, consolidate and cut money.

Is a \$15 million reduction in funding for Health Professions Program, is this reduction consistent with the need to support increased training of primary care providers that is being generated by the move toward health care reform, and have you submitted any kind of a legislative package to the authorizing committees for this kind of consolidation?

Dr. LEE. Senator, I should just add in the beginning that Dr. Sumaya was not present as the Agency head when we made those decisions, so the responsibility falls elsewhere. He has the job of developing recommendations which we will be submitting to the Congress as to how this can be achieved over a 2 year period. But he was not responsible for that consolidation initiative.

Senator HARKIN. I understand. Well, again, I look forward to getting from you some idea on how this consolidation and cut is going to meet the kind of goals toward more primary care people out there and other health care professionals with the kind of cuts that are coming. Obviously, we want to move away from the specialist. We do not want to stop it but we want to get more primary care.

Dr. LEE. In dealing with that, one of the reasons we made the decision with respect to those consolidations, was to make the management from the institutional standpoint somewhat easier, but also from the standpoint of the Public Health Service and also in health care.

In the Health Security Act, there is \$400 million of additional funding for both physician and nurse training. It would include areas like geriatrics, which is very important. And we felt with the Health Security Act provisions that it was possible to make some consolidations in these programs, as proposed.

Senator HARKIN. Let me just ask you a couple of other things, then. One item I am very concerned about is the maternal and child health block grant formula. I understand there is a study underway to revise that, and I just wonder what the status of that study might be, if you know at this point, and if you do not you can respond to me in writing.

Dr. SUMAYA. Yes; the study at this point is they have received from the study panel recommendations and discussion on the topic and that has gone to the bureau. The bureau then is reviewing it and will be passing that on to me for review. So it is under internal review of HRSA at this point.

Senator HARKIN. And will we be able to take a look at that within the next month or so?

Dr. SUMAYA. I would assume that would be shortly.

Senator HARKIN. Because obviously I would be interested in seeing what those recommendations are in terms of our appropriations process for this year.

Dr. SUMAYA. Absolutely.

Senator HARKIN. Dr. Satcher, there have been a lot of stories lately about new strains of bacteria that are out there, new strains of pneumonia, drug resistance. I think one of the weekly news magazines had a big story about how we have been giving antibiotics for years, but a lot of these bugs slip through and they become more drug resistant and it raises the specter of a major threat to public health from this.

I do not know, maybe it is my imagination, but it just seems to me that this winter there has been an incredible amount of pneumonia and that type of thing, influenza going around this country. And I am just wondering what you make of that and whether or not you believe the budget that you have for the CDC is adequate to respond to these new threats to public health? How valid are these threats?

I guess that is my question: How valid are these threats? And second, do you feel your budget is adequate to respond to those if, God forbid, we do have a major outbreak?

Dr. SATCHER. First, Senator, I feel that the threats are quite valid. There are several areas in which we have seen them. You mentioned pneumococcal bacteria and staph, where we have seen increasing resistance. Tuberculosis also. One of the problems in controlling tuberculosis is the increasing multidrug resistance of tuberculosis. There are several factors involved and we do not fully understand them. I think that our molecular geneticists are looking at the rate at which viruses and bacteria are mutating and, therefore, gaining resistance to drugs.

Some of it has to do with the social situation. I mean, when it is very difficult, for example, to complete a course of therapy for tuberculosis you increase the possibility of the development of multidrug resistance. Obviously, HIV infection and changes in the immune status also has an impact on that. And so it is a real problem and a real concern to CDC. That is why we have listed as one of our priorities urgent threats to health. And with new emerging and reemerging infections being near the top of that list, we are continuing to strengthen our laboratories and to strengthen our personnel in infectious diseases.

We face the same challenges that everyone else does in terms of operating in an environment where we know that we have to streamline our operations, but at the same time we have to improve the quality of that operation. We just designated a new tuberculosis laboratory last week at CDC that will significantly improve our ability to deal with that problem.

So it is true that we are trying to manage a decreasing FTE load and to manage a very tight budget, but we believe that there are strategies that we have in place and there are relationships that we have with academic health centers, with State and local health departments—and globally, we have global surveillance laboratories that we are developing relationships with.

I was in Puerto Rico yesterday to help launch the measles elimination campaign, but in the process I visited the Dengue Fever Laboratory that we have there, and all over Latin America and the Caribbean we have laboratories that we are relating to to help us detect early changes in viruses and bacteria.

So we are trying to compensate for some of our budgetary problems by strengthening relationships and strengthening our organization. So we do believe that we can stay on top of this problem, but it is certainly real.

Dr. LEE. It is also important, Mr. Chairman, to note the relationship between CDC, FDA, and NIH in this area. With immunization, for example, CDC carries on a surveillance, and when they detected the new strains coming in, they and NIH moved in to work with industry to develop new vaccines. FDA got those approved. Medicare then pays for the vaccination of the elderly. And this year with the new strain there was more influenza. Medicare also pays for the pneumococcal vaccination.

So that those preventive strategies, which when we learn what to do we get them included in benefits—I mean, Congress includes them, we do not do that without Congress' authorization—but those linkages are very important, and I think that we are moving to strengthen those with the Health Care Financing Administration, with NIH, with CDC, and with FDA, in this area. But it is a very important and very serious threat, and we share your concerns.

Senator HARKIN. So the threat is real, and I guess I just wondered if in your professional judgement you believe the budget is adequate to respond to these in the future? I mean, you are getting cuts in FTE's, right?

Dr. SATCHER. We are having to reduce FTE's at CDC, and I think one of the situations with our budget, of course, is that CDC's budget from 1993 to 1994 experienced a significant increase. And this year, of course, our budget is fairly flat. What we are trying to do is to assess changes that we are making internally, changes in our relationship with laboratories throughout the world, our relationship with NIH and FDA, and trying to see how that is impacting our work. So we are going to operate within our budget and I think we are going to continue to make progress in those areas.

My professional judgment is that it is a very serious threat to the health of the American people and to the health of people throughout the world, and they are inseparable.

Senator HARKIN. I am going to refer to some questions that I had submitted and got back answers on this, Dr. Satcher, and I want to get this complete because I want to know how we should proceed on this. In order for CDC to cover these emerging infectious disease threats, what is required?

Your response was that the CDC plan would require an estimated \$100 million annually, more than one-half of which would be provided to State and local health departments for surveillance, applied research, and prevention activities. We must position ourselves to detect and investigate these emerging infections early and intervene effectively to avoid severe illness and premature death, as well as major health care costs.

Again, I am concerned about making sure that we have adequate money. I would liken it to the floods. I mean, if we had our levies just a couple of feet higher, you know, we would not have had all that damage that we had. It is now being responded to, but it is a little late. And this is what I am concerned about here, is if we have an outbreak and if Congress is not in session, or if it is during an August break or maybe we go out in October for elections and we are out of session, and like the hantavirus, if you have to come back for additional moneys and we are not here, I am concerned about that.

I do not mean to raise any undue fears, but it would seem to me that—I just want to be assured that we would be able to respond adequately.

Dr. SATCHER. I do not think you are raising undue fears. I think they are appropriate concerns. The information that you have been provided in terms of our feelings about needs in the future have just, in fact, been developed by our staff in the National Center for Infectious Diseases over the last 2 weeks, and we have just reviewed those findings so they were not in any way a part of the consideration for this year's budget request.

But when I say that we are going to continue to assess our needs in this area, that continuing assessment certainly is reflected in what people in the National Center for Infectious Diseases have now projected the needs are going to be over the next few years. We have to look at that, as Dr. Lee said. We have to look at it in relationship to NIH and FDA. We have got to look at it in terms of how we manage the overall approach to this problem within the Department.

So I agree that it is a serious problem and a serious concern.

Dr. LEE. It goes back to the original question you asked me, Senator Harkin, because in the Health Security Act with the core public health funding that is possible. We could go a long way to meeting these needs, particularly at the State or local level. But we must work with you to really identify the source of funding for those initiatives.

ALCOHOL ABUSE

Senator HARKIN. I appreciate that.

Speaking of hardcore drug use, Dr. Johnson, when we talk about substance abuse, and this is a speech I usually give on the Senate floor every time we start talking about drug interdiction and death penalty for kingpins and all that kind of stuff, and all this new high-tech radar and everything to intercept planes coming in carrying cocaine, I have to get up and respond and talk about the single most abused drug in our country today.

It does not happen to be illegal. It happens to be legal. But it is the most abused and it causes the most deaths, accidents, crime,

injuries, and, of course, I am talking about alcohol, 30 times more prevalent than heroine or cocaine addiction. There has been a tendency to forget that alcohol is our No. 1 substance abuse. While illegal drug problems account for only about one-third of treatment admissions, alcohol problems account for two-thirds of admissions.

The President's budget has a \$310 million increase to treat hardcore addicts, and the Office of National Drug Control Policy proposes that the \$310 million increase be confined to the treatment of addicts who abuse illegal drugs.

Well, what about that? Why should we not use that for other things, too? How about alcohol abuse?

Dr. JOHNSON. Mr. Chairman, this Department is very much committed to responding to the issue of alcohol. The block grants, which is now over \$1 billion, certainly covers alcohol services as well as those for other drugs. In addition, the programs funded by the Center for Substance Abuse Prevention clearly focus on both alcohol and other drugs. SAMHSA clearly has a major focus on alcohol and other drugs.

In terms of the hardcore initiative, there are ongoing discussions within the administration about the exact parameters of heavy use which need to be worked out.

SMOKING AND HEALTH

Senator HARKIN. I see. Well, let me bring up one other—in the interests of time, we have got to move fairly rapidly. I forgot what time it was here.

SUBSTANCE ABUSE

How about smoking? What are you going to do about smoking? What is your Department looking at in terms of smoking?

Dr. JOHNSON. We share concerns about smoking with the other Public Health Service agencies. In terms of smoking by youth, the Congress passed legislation within the block grant to penalize States which do not put into place measures to decrease access to tobacco products by youth. This is a major concern of ours, and we are in the process of finalizing regulations to implement this requirement. As soon as the process is completed, I will share the package with you and your committee.

We have been concerned about smoking for a long time, since we see it as a gateway drug. There is substantial research that supports this finding. In addition, we are concerned about tobacco use by pregnant women, because low birth weights are related to smoking during pregnancy. Tobacco receives considerable attention in our programs for pregnant women who are substance abusers.

Dr. LEE. As you know, Senator Harkin, CDC is the lead agency in the Public Health Service on smoking and health with their Office of Smoking and Health. I mentioned the initiative with Dr. Satcher and Dr. Elders. I mentioned the recent guideline release for schools; also, the funding by CDC and the National Cancer Institute of State tobacco control programs. But Dr. Satcher may want to say a word about that, as well, because CDC is the lead in this.

Senator HARKIN. Before you get to that, though, I want to pick up on what Dr. Johnson said. I will get to that in a second.

SMOKING REGULATIONS

The act of 1992, Public Law 102-321, which I was involved in, requires the States to enforce laws prohibiting the sale of tobacco to anyone under the age of 18. States that fail to meet the requirements can lose up to 40 percent of their Federal alcohol and drug abuse treatment funds. That has been almost 2 years. And you tell me you are in the process of developing final regs. How soon?

Now, obviously, you have not been there all these 2 years. But you have been there 1 year now, so we have got 1 year of it.

Dr. JOHNSON. We have received considerable responses to the notice of rulemaking around this issue, especially from the States. And I should point out that there is considerable concern from the National Governors' Association, as well as many others, about the smoking regulations. We need to pay particular attention to the language of the final regulations and the policy issues they involve as we respond to the several hundred comments that we have received on the notice of proposed rulemaking.

ANTISMOKING CAMPAIGN

Senator HARKIN. Very good. Getting back, then, to Centers for Disease Control and Prevention, on smoking, it seems that we had proposed and asked for a set-aside, I believe—I can be corrected by staff—on counter-advertising on smoking. The report language that we had in our bill last year encouraging CDC to take steps to promote counter-advertising to youth.

I was with Dr. Koop this morning, and it is his judgment—and he obviously, as you know, has been involved in an antismoking campaign for a long time—that kids really decide to smoke at a very early age, 8, 9, 10 years of age. They may not start smoking until 13 or 14 when they are able to access it. But they make the decision earlier on, and that is through advertising and Old Joe Camel and all those kinds of things.

It has been proven in the past—in California where they started an antismoking counter campaign—that it was very effective. I just again wonder what you are looking at and if you are moving ahead any in that area in terms of counter advertising, especially for school-aged children.

Dr. SATCHER. Yes; I think this year for the first time in the 30 years of the Surgeon General's report, which is prepared by CDC, we targeted the problem of tobacco in youth. And we have worked with all of the States now. I think 17 States, plus California, have established tobacco control programs. We have now supported 32 more States and Washington, DC, so that all 50 States now have some type of tobacco control program.

What we consider to be marketing antismoking behavior is a part of the strategy. There are releases that go along with that. Some of them are paid for by the States themselves; in fact, most of them. Some of them are paid for privately. But there is a major effort being coordinated through the leadership of CDC.

When Surgeon General Elders and I have our national television hookup next week, that will be a major focus of our discussion with youth and leaders of youth programs throughout the country in terms of what we need to do in the future. So I think we are moving in the right direction.

I must say that when we had our meeting with the press in New York on February 22 to talk about that we had some very interesting and in some ways disturbing reports where studies have been done, for example, showing the fact that it was still very easy for teenagers to purchase cigarettes in this country. In one study, over 60 percent of teenagers who tried to purchase cigarettes succeeded with no problem. They were even able to purchase single cigarettes. In other words, open packages so that they could afford them.

So we have some serious problems in that area, but we are certainly committing a lot of our time and effort to counteracting that problem.

Dr. LEE. On the counter-ads, too, Senator Harkin, one of the things we have been finding is that the public service ads do not exactly come on in prime time, and that is really the basis for this question about whether we should pay for those ads so we can get them on during prime time. That is one of the questions we are really looking at.

One other thing I wanted to mention, it is not only smoking, it is smokeless tobacco or chewing tobacco. And in the testimony I heard from Alaska Natives, kids at the age of 5 and 6 years old are chewing tobacco. Apparently, the average age when kids start chewing tobacco is 9. They start smoking a little later. But we have to be as concerned with chewing tobacco as we do with cigarettes, and this is something we are going to be looking at as well.

Senator HARKIN. Obviously, one of the biggest sources of cigarettes for kids under the age of 18 are vending machines. Now, I know that certain States have rules that you have to have a vending machine in the view of the person behind the counter. Of course, if the person behind the counter moves you cannot see it, and you know how that goes. And I am just wondering if we might not want to take a look at that as an aspect of further prohibition.

Dr. JOHNSON. Let me say that in some instances where stores have been very responsive, they have installed alarm systems on their vending machines so that an alarm sounds whenever the machine is used, therefore, alerting store personnel to pay attention to who is buying the cigarettes.

Senator HARKIN. Very good. There are things that we can do.

Mr. Vladeck, you and I had a chance to speak the other day, and in the interests of time I may just want to say one thing to you, and that is in terms of rural telemedicine projects that were in the fiscal year 1994 Appropriations Committee report, what is the status of those?

Mr. VLADECK. We have set aside a considerable amount of money as part of our general research and demonstration solicitation for this fiscal year. We have convened a special panel. We would hope to make awards for a number of projects before the end of May for about \$5 million or \$5.5 million as a part of that solicitation. This

is the bulk of the money that you earmarked for telemedicine in this year's appropriation.

There are a couple of other projects we have already funded and some we are still looking at in addition.

Senator HARKIN. Very good. I appreciate that.

Is there any last thing that anyone wanted to bring up, specifically to my attention or to the attention of the staff, before we recess or adjourn.

Dr. LEE. We just want to thank you.

Senator HARKIN. Well, thank you, Dr. Lee. Thanks for your patience and being here this morning. We look forward to working with you.

Dr. LEE. Thanks very, very much.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question. What is the total amount of delayed obligations proposed in the Department's FY 1995 budget and how does this compare with fiscal years 1992, 1993, and 1994?

Answer.

(\$'s in thousands)

1992	1993	1994	1995
\$2,804,447	\$900,000	\$892,711	\$1,394,262

Question. Provide a table for fiscal years 1989 through 1995 showing total funding for substance abuse programs throughout the government broken down by program.

Answer.

SUBSTANCE ABUSE--TOTAL FEDERAL GOVERNMENT SPENDING

(Dollars in millions)

	1989	1990	1991	1992	1993	1994	1995 P B
Dept. of Health and Human Services:							
Public Health Service:							
FDA	\$6.5	\$7.2	\$6.5	\$6.7	\$6.8	\$6.8	\$6.8
HRSA	0.3	0.2	13.5	16.7	20.9	33.4	38.7
IHS	49.9	65.8	74.0	78.0	84.5	90.9	105.8
CDC	20.0	25.2	29.3	28.6	31.2	36.6	36.6
NIH	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NIDA	228.1	329.8	383.7	399.2	404.2	425.2	444.3
NIAAA	120.1	149.2	158.1	171.7	176.4	173.6	173.6
NIMH	34.0	47.0	56.8	62.2	64.7	64.1	64.1
Sub. NIH	382.2	525.8	598.4	633.1	645.4	662.9	682.0
SAMHSA	748.6	1,275.5	1,461.5	1,533.1	1,626.1	1,703.7	1,988.7
Sub. PHS	\$1,207.4	\$1,899.7	\$2,183.1	\$2,296.3	\$2,414.9	\$2,534.4	\$2,858.5
Administration for Children and Families	\$43.9	\$62.0	\$108.3	\$111.0	\$111.2	\$121.2	\$121.2
Health Care Financing Administration	490.0	610.0	680.0	750.0	850.0	950.0	1,070.0
Social Security Administration	1.9	2.5	3.1	4.9	4.6	20.0	36.0
Subtotal, HHS	\$1,743.2	\$2,574.1	\$2,972.5	\$3,182.2	\$3,380.6	\$3,825.6	\$4,085.7
Office of National Drug Control Policy							
Operations	\$3.5	\$12.1	\$17.3	\$18.7	\$15.2	\$11.7	\$10.0
High Intensity Drug Trafficking Areas	0.0	25.1	82.0	88.0	88.0	86.0	98.0
Special Forfeiture Fund	0.0	115.0	6.0	20.0	15.2	12.8	7.5
Subtotal, ONDCP	\$3.5	\$152.2	\$105.3	\$124.7	\$118.4	\$110.5	\$115.5
Dept. of Labor	\$38.6	\$46.0	\$60.9	\$61.5	\$65.1	\$64.8	\$80.5
Dept. of Education	376.3	602.8	683.1	714.7	700.8	599.1	782.3
Dept. of Agriculture	6.5	6.7	16.1	15.9	28.9	30.7	31.0
Dept. of Defense	501.8	799.1	1,042.5	1,228.0	1,140.7	868.2	874.2
Dept. of Veterans Affairs	242.0	305.6	610.6	841.7	901.5	940.3	981.1
Dept. of Justice	2,470.6	3,827.8	3,842.1	4,240.7	4,803.3	4,762.5	5,184.3
Dept. of Treasury	702.5	905.1	977.6	1,097.3	1,040.5	1,102.6	1,053.6
Dept. of Transportation	643.0	553.1	749.6	487.9	355.3	373.8	307.3
Dept. of State	122.6	244.0	257.6	220.1	200.2	115.7	232.1
Agency for International Development	16.4	59.9	196.7	258.0	139.8	44.9	0.0
U.S. Information Agency	2.8	3.4	7.3	9.7	9.3	9.8	10.0
Dept. of Interior	13.4	29.4	35.7	45.2	40.6	38.7	34.1
Corp. for National and Community Service	10.1	10.5	12.5	10.0	9.7	28.5	43.0
Small Business Admin.	0.0	0.0	0.1	0.1	0.2	0.2	0.2
Housing and Urban Development	8.2	108.5	150.0	165.0	175.0	315.0	315.0
The Judiciary (U.S. Courts)	208.8	258.1	284.1	359.9	405.6	452.9	505.5
Sub. Non-HHS	\$5,366.9	\$8,047.6	\$9,041.8	\$9,858.4	\$10,132.9	\$9,858.2	\$10,549.7
TOTAL Substance Abuse	\$7,110.1	\$10,621.7	\$12,014.3	\$13,020.8	\$13,513.5	\$13,483.8	\$14,635.4

Question. Break out AIDS funding by agency in the Public Health Service.

Answer.

HIV/AIDS

PHS HIV/AIDS Funding History

(Dollars in millions)

	1989	1990	1991	1992	1993	1994	1995
	Actual	Actual	Actual	Actual	Actual	Approp	Pres Budget
PUBLIC HEALTH SERVICE:							
FDA.....	\$73.8	\$57.4	\$63.4	\$72.3	\$72.6	\$72.4	\$72.4
HRSA:							
Ryan White:							
Title I.....	\$0.0	\$0.0	\$66.9	\$120.5	\$184.8	\$325.5	\$364.5
Title II.....	0.0	0.0	66.8	106.6	115.3	183.9	213.9
Title III.....	0.0	0.0	44.3	48.7	48.0	48.0	67.0
Title IV.....	0.0	0.0	0.0	0.0	0.0	22.0	27.0
Sub, Ryan White.....	\$0.0	\$0.0	\$218.0	\$275.8	\$348.0	\$579.4	\$672.4
Other HRSA AIDS.....	\$59.9	\$112.5	\$47.9	\$40.8	\$42.3	\$28.4	\$28.4
Sub, HRSA.....	\$59.9	\$112.5	\$265.9	\$316.6	\$390.3	\$607.8	\$700.8
IHS.....	\$0.8	\$2.7	\$1.8	\$3.2	\$3.3	\$3.6	\$3.6
CDC.....	\$377.6	\$442.8	\$497.0	\$479.6	\$498.3	\$543.3	\$543.3
NIH.....	\$717.5	\$908.1	\$1,014.5	\$1,047.5	\$1,071.5	\$1,301.0	\$1,379.1
SAMHSA.....	\$58.2	\$50.0	\$29.5	\$26.0	\$25.7	\$28.1	\$33.0
AHCPR.....	\$6.8	\$8.5	\$10.3	\$10.1	\$9.6	\$10.6	\$12.0
OASH	\$6.4	\$7.7	\$5.9	\$4.8	\$5.3	\$5.3	\$5.3
Subtotal, PHS.....	\$1,301.0	\$1,589.8	\$1,888.2	\$1,960.1	\$2,076.6	\$2,572.1	\$2,749.4

Question. Provide a detail of administrative expenses by object class for Department agencies for fiscal years 1993, 1994, and 1995.

Answer. (Refer to the question and answer following the next one for this answer).

Question. What is the status of the HHS compliance with Executive Order 12837 which requires all agencies to submit FY 1995 budget requests that reflect no less than a 6 percent reduction in administrative expenses from the amounts made available for FY 1993? Provide an analysis of proposed Departmental reductions in the FY 1995 budget that result from this Executive Order.

Answer. While Executive Order 12837 requires that all agencies submit FY 1995 budgets to OMB that reflect no less than a 6 percent reduction in administrative expenses from amounts made available for FY 1993, budget guidance from OMB directed HHS to use a different method for estimating our administrative expenses. The OMB guidance specifically asked us to adjust administrative expenses for inflation, and then reduce the adjusted rates to an average annual increase of no more than 3 percent from FY 1995 through FY 1999. HHS complied with this guidance from OMB when preparing our FY 1995 estimates. As can be seen from the attached chart, significant reductions have been taken in administrative costs throughout HHS. Exceptions to the OMB guidance have been made in cases where significant administrative investment is critical to the function and mission of the Department. For an analysis of HHS reductions in administrative expenses, please see attached chart.

Exceptions

SSA's administrative expenses have been increased by approximately \$155 million. More than half of this increase, or \$104 million, is for SSA's automation activities. In addition, SSA will require an additional \$51 million in administrative dollars for workload-related increases for medical consultants, training and travel for processing claims and appeals, supplies, telephones, utilities, and postage for SSI claims.

HCFA's administrative expenses, like those of the Social Security Administration, are a function of both inflation and increasing workloads. If you factor in these two components, HCFA's 3.8 percent increase from FY 1993 to FY 1995 translates to a decrease of 5.5 percent based upon Office of Management and Budget assumptions.

OMB Assumptions about HCFA Administrative Expenses

Administrative Expenses		Factors	
		<u>FY 1994</u>	<u>FY 1995</u>
FY 1995	\$1,893,549,000	Inflation... 2.7%	2.9%
FY 1994	1,903,144,000	Workload... 1.99%	1.92%
FY 1993	1,824,226,000		

Source: Office of Management and Budget

Factoring in both inflation and workload increases, the FY 1993 amount of \$1,893,549,000 is converted to a FY 1995 target of \$2,003,925,000. HCFA's budgeted spending level is 5.5 percent below this target. This level will be achieved while HCFA re-engineers its work environment to reach its FTE reduction targets, to consolidate its headquarters in a new single site, and to develop an agency-wide comprehensive strategic plan.

See Insert, ("Analysis of Change in Administrative Expenses")

ANALYSIS OF CHANGE IN ADMINISTRATIVE EXPENSES

(Budget Authority in Thousands)

Change from 93 to 95 Object Class	PHS:		TOTAL					ACF		OS		TOTAL L/H/SE
	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS	HCFA	SSA	AOA		
Travel (21.0).....	226	(117)	3,326	(106)	(72)	230	3,487	384	11,305	151	140	15,056
Transportation of Things (22.0).....	(14)	485	896	30	1	22	1,420	161	2,294	15	27	3,908
Rental Payments to Others (23.2).....	(162)	289	2,945	7	1	0	3,080	(4,685)	186	0	2	(1,251)
Communications, Utilities, and												
Miscellaneous Charges (23.3).....	(106)	1,728	4,257	1,405	(2)	244	7,526	6,661	30,451	905	(13)	346
Printing and Reproduction (24.0).....	240	251	673	105	(201)	154	1,222	(549)	2,058	1,585	32	(33)
Consulting Services (25.1).....	1,985	(1,168)	(674)	(665)	0	0	(522)	16,490	3,908	45,268	3,160	(134)
Other Services (25.2).....	38,373	(25,219)	(11,776)	(11,741)	(964)	3,898	(6,829)	54,479	84,546	(33,394)	(259)	2,314
Purchases from Govt. Accts. (25.3).....	(43,087)	0	(89,976)	0	0	(7,413)	(140,476)	(2,868)	17,928	0	0	(456)
Operation of GOCOs (25.4).....	0	0	1,161	0	0	0	1,161	0	0	0	0	431
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	929	(507)	6,666	(321)	(3)	(10)	6,754	(750)	2,091	170	23	8,224
TOTAL CHANGE	(1,616)	(24,258)	(81,902)	(11,286)	(1,240)	(2,875)	(123,177)	69,323	154,768	14,700	3,112	119,715

Question. Executive Order 12837 requires all agencies to include a separate category for "administrative expenses" when submitting their appropriation requests to the Office of Management and Budget for fiscal years 1994 through 1997. Provide a detail of "administrative expenses" for Department agencies for fiscal years 1993, 1994, and 1995.

Answer. In the formal budget guidance provided by OMB for FY 1995 in the form of OMB Circular A-11, OMB did not require that Department Agencies include a separate category for "administrative expenses" when submitting their appropriation requests to the Office of Management and Budget. The administrative expenses portion of the HHS salaries and expenses exhibits has been provided in the attached table.

See Insert, ("Summary of Administrative Expenses")

SUMMARY OF ADMINISTRATIVE EXPENSES

(Budget Authority in Thousands)

FY 1993		PHS:				TOTAL				ACF	AoA	OS	TOTAL L/H/S/E
Object Class	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS	HCFA	SSA				
Travel (21.0).....	3,094	11,791	17,718	1,641	444	807	35,495	5,094	20,666	3,500	280	4,335	69,370
Transportation of Things (22.0).....	1,230	3,071	3,217	72	48	86	7,724	270	4,826	110	45	365	13,340
Rental Payments to Others (23.2).....	162	1,180	4,845	167	8	0	6,362	4,685	454	0	0	16	11,517
Communications, Utilities, and Miscellaneous Charges (23.3).....	3,148	16,070	37,418	1,339	503	1,001	59,479	7,758	240,608	3,095	357	4,025	315,322
Printing and Reproduction (24.0).....	510	4,611	16,287	2,137	2,031	201	25,777	6,531	20,136	1,000	209	1,725	55,378
Consulting Services (25.1).....	10,662	1,817	29,777	17,500	0	0	59,756	10,128	191	34,578	2,013	881	107,547
Other Services (25.2).....	34,399	57,331	260,361	100,497	4,313	10,378	467,279	1,774,697	132,215	69,205	2,653	6,407	2,452,456
Purchases from Govt. Accts. (25.3).....	43,087	0	620,646	0	0	7,413	671,146	13,129	156,500	0	0	14,435	855,210
Operation of GOCOs (25.4).....	0	0	1,499	0	0	0	1,499	0	0	0	0	730	2,229
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	2,179	10,180	117,376	649	370	221	130,975	1,934	28,664	580	76	1,639	163,868
TOTAL, Administrative Expenses	98,471	106,051	1,109,144	124,002	7,717	20,107	1,465,492	1,824,226	604,260	112,068	5,633	34,558	4,046,237

HARD-CORE DRUG INITIATIVE

Question. When we talk about substance abuse we're not just talking about heroin and cocaine. We're also talking about alcohol, which is 30 times more prevalent than heroin or cocaine addiction.

Since the beginning of the war on drugs, there's been a tendency to forget that alcohol is the Nation's number one substance of abuse. While illegal drug problems account for only one-third of treatment admissions, alcohol problems account for two-thirds of treatment admissions.

The President's budget includes a \$310 million increase in the Substance Abuse Block Grant targeted to treat "hard-core" addicts. The Office of National Drug Control Policy (ONDCP) proposes that the \$310 million increase be confined to the treatment of addicts who abuse illegal drugs.

Secretary Shalala, what is your position on this issue?

Answer. We are currently discussing with ONDCP the exact parameters of our "hard-core" treatment initiative. We recognize the importance of alcohol abuse, which, largely by the greater numbers of abusers, has a greater impact than drug abuse in terms of national economic, health, and other societal costs. We understand that, in certain States, alcoholism may be a greater problem than drug abuse. We also recognize the public's special concerns that illegal drug use, especially by hard-core users, is disproportionately contributing to crime, senseless violence, and transmission of deadly diseases such as HIV/AIDS. In reality, drug use and alcohol use are often inextricably linked. According to Drs. Norman Miller and Mark Gold, of those addicted to marijuana, 36% are alcoholics; of those addicted to cocaine, 84% are alcoholics; of those addicted to opioids, 67% are alcoholics. In essence, alcoholics are multiple drug addicts who combine and substitute one drug for another.

BACKLOG OF SOCIAL SECURITY DISABILITY CLAIMS

Question. Why, with all the money and staff we are putting into the disability case processing and automation are you projecting that service will get worse rather than improve between now and the end of fiscal year 1995.

Answer. By far the biggest challenge for SSA over the last several years has been the unprecedented growth in disability workloads. Over the last five years (1989-1994) initial applications increased by 72%. In FY 1995 we predict that annual applications will grow to nearly 3 million, an 8% increase over FY 1994.

Despite this tremendous growth in recent years, we have successfully managed to prevent parallel growth in waiting times for disability applicants. In fact, in FY 1993 the average waiting time for an initial decision decreased (from 104 days to 97 days), despite a 12% increase in applications. We now expect much better service levels in FY 1994 than we predicted last year, however, we do expect some deterioration in average initial decision times.

We have worked to put in place a comprehensive plan to boost our capacity to deliver services and provide real long term solutions to deal with growing workloads. In the short term, we will invest dollars and FTE in disability and automation, continue research to understand the causes of application increases, and support various management streamlining initiatives. Over the longer term, we intend to re-engineer the disability process to ensure our program continues to meet the needs of changing populations. In FY 1995, SSA will process 15% more claims in the State Disability Determination Services (DDSs) and 41% more hearings in the Office of Hearings and Appeals (OHA) compared with FY 1992.

Unfortunately, we will not be able to keep up with the application rate in the shorter term. Although we will increase our capacity to process more cases, we expect that disability backlogs will increase by about 380,000 claims in the State Disability Determination Services (DDSs) and by about 40,000 claims in the Office of Hearings and Appeals (OHA). Likewise, we expect processing time to increase by 40 days in the DDSs (to 154 days) and by 15 days in OHA (to 342 days).

Question. What do we need to do to turn this problem around and give our constituents the service they deserve?

Answer. Our goal is to drastically improve disability services. Unfortunately, we cannot improve this service overnight, even with additional resources. However, we are confident that our strategy of combining short and longer term initiatives is the most responsible approach to meet the needs of this growing beneficiary population. In FY 1995, this requires continued funding to support our investments in disability including full funding to sustain our multi-year investment in a state-of-the-art computer system to better serve our beneficiaries.

SSA has recently presented a draft plan to reengineer the disability process. Reengineering the disability process is central to our long term strategy to improve services. Over the next two months, SSA will solicit feedback from a wide range of constituents including the Administration and Congress, SSA components and the State Agencies, and of course, our beneficiaries and future customers. The final design will take into consideration the comments we receive during this feedback period. By September, we hope to begin implementing a wide range of activities in our plan. We are confident that this effort, combined with other longer term initiatives, will enable us to better serve a growing base of customers.

COMMUNITY SERVICES DISCRETIONARY PROGRAM

Question. I note with some concern that the Administration is recommending the elimination of the Office of Community Service Discretionary Program.

Was this decision made because of your desire to consolidate programs or was it made after consideration of the effectiveness of these programs?

Answer. We have proposed to consolidate and expand upon the Community Economic Development program and the Job Opportunities for Low Income Individuals program through a new Community Initiative Program. Our budget also proposes to eliminate a number of the small, discretionary programs administered by the Office of Community Services. These eliminations address earlier concerns of the Congress to reduce the number of small, categorical grant programs.

In this time of renewed interest in the plight of the homeless, how can the Administration justify the elimination of the Emergency Community Services Homeless Grant program?

Answer. These eliminations are not meant to take away benefits from any particular group, but to address the concerns in the Congress over the number of small categorical grant programs. States may choose to use block grant funding for some activities previously funded through these separate programs. Our reauthorization proposal would require States to include a plan for serving the homeless in their application for block grant funds. In addition, the FY 1995 budget for the Department of Housing and Urban Development includes significant increases in spending for the homeless.

Do you have any information to share with the committee concerning how these funds are spent in providing social services and homeless prevention services to those most in need?

Answer. In FY 1994, funds appropriated for the Emergency Community Services for the Homeless Program were distributed to the 57 States and Territories that receive funds under the Community Services Block Grant Program as well as to a number of Indian Tribes and tribal organizations. These funds may be used for a number of purposes including: expanding services to families and individuals who are homeless; providing assistance to homeless individuals in receiving social services; and, providing for renovation of buildings used to house homeless individuals. States may choose to use block grant funding for these activities, and the Department's reauthorization legislation encourages such action.

If many of the discretionary programs can be funded through Community Services grants to the states, why was the CSBG program not substantially increased to accommodate these increased program responsibilities?

Answer. In order to fund priority investments while remaining within the discretionary budget caps, the Administration held funding levels constant for most programs and actually reduced funding for a number of programs.

Do you plan to proceed with this consolidation, even if it is not addressed in reauthorizing legislation?

Answer. Our proposed reauthorization legislation includes both a consolidation proposal for the Community Initiative Program and a number of changes in discretionary activities funded. We would encourage the Congress to approve our proposal.

Background: Overall funding for Community Services activities declines by \$29 million, from \$464 million appropriated in 1994 to \$435 million requested for fiscal 1995.

OTHER RESOURCES AVAILABLE FOR LIHEAP

Question. The Administration is also justifying the LIHEAP cut by saying that low-income families have other sources of income to help them.

They claim that the Earned Income Tax Credit (EITC) will increase income for working families by \$21 billion between 1994-1998.

Isn't it true that the purpose of the EITC increase was to raise the income of working families closer to or above the poverty line?

Answer. Yes. Increases in the Earned Income Tax Credit (EITC) were intended to ensure that families with earnings from at least one full-time minimum-wage worker, who also receive Food Stamps, would not fall below the poverty level when these benefits are included. Families with incomes up to \$27,000 qualify for some level of the credit. The Omnibus Budget Reconciliation Act of 1993 made an additional \$20.8 billion available for the EITC over the next five years to low-income working families. This means an increase in the maximum credit for a family of four of \$1,372, from \$1,998 to \$3,370. Individuals and couples without children whose incomes fall below \$9,000 are also eligible for a new, smaller credit.

Question. Secretary Shalala, the Head Start program has grown from a \$1.2 billion program in FY 1989 to \$3.3 billion in FY 1994. Now, in FY 1995, the budget requests \$3.9 billion, or an increase of \$700,000. In just five years, this program has increased by \$2.7 billion. That is quite an increase, and frankly, there are doubts that the system can absorb \$700,000 in FY 1995, on top of all of the other increases we have provided.

What is your response to those that say that there are insufficient numbers of trained personnel to operate new or expanded centers?

Answer. We are not aware of any shortage of individuals with the qualifications necessary to work in a Head Start setting. We will also continue providing CDA training to teacher aids to help provide promotion potential to current staff.

What is your response to those who say that they are having a difficult time locating children to participate in the program?

Answer. We have asked grantees to assess their community's needs before they make the decision to expand services. Obviously, we only want to increase the number of children served where the need for that expansion exists. In FY 1993 Head Start served 714,000 children. That is about 40% of the at least 1.8 million income eligible three or four year olds. So there are still unserved children out there for local programs to serve. And the vast majority of Head Start programs are not having a difficult time locating children to serve. In fact, most grantees have waiting lists.

What is your response to those who say that before further expansion of Head Start, more attention should be given to the quality issues -- including salaries of Head Start workers?

Answer. We don't see this as an either/or issue. It is our desire to ensure that the maximum number of eligible children and their families can have the opportunity to participate in a quality Head Start program. Therefore, we are making a significant and continued investment in Head Start quality while at the same time expanding the program. At least 25% of the increase in annual appropriations (over the adjusted base) will be spent on quality improvements including salary increases for Head Start workers. In addition, grantees can choose to spend even more on quality if they determine it would be beneficial to their program.

The reauthorization of Head Start, which is currently under discussion, would allow for the purchase of facilities by Head Start grantees. Who will own those facilities -- the federal government or the grantees?

Answer. The authority to purchase facilities is already a part of the Head Start Act. It was included as part of the 1992 amendments. The government will maintain reversionary interest in all facilities bought with grant funds and a notice of the government's interest will be filed in the local courthouse. No facility can be sold or transferred without government concurrence.

Will the purchase of facilities create a problem with regard to downsizing a program or expanding a program as demographics change?

Answer. Facility purchase should not create significant difficulties for a program that is expanding or changing in response to demographics. Rather, it will help to prevent the current problem faced by grantees who cannot find suitable facilities to rent and those who have been forced to move frequently. Facility purchase is only one of several options for obtaining facilities. We expect grantees will choose the option that best meets the needs of their program and their community.

CBO RESCORING

Question. The Congressional Budget Office has just scored the President's 1995 budget and found that it's \$3.1 billion in outlays over the discretionary caps.

Clearly, some cutting and trimming will have to be done to the President's budget to put it in compliance with the Budget Enforcement Act.

If our subcommittee has to take some of those cuts, as expect it will, my assumption most of those cuts will have to be made at HHS, because as I said earlier, that's where the outlays are. Secretary Shalala, will you be prepared to work with me and my staff over the next several months as we work on our Fiscal 1995 bill?

Answer. We will be happy to work with you and the subcommittee as you deliberate over the President's 1995 budget.

OFFICE OF THE GENERAL COUNSEL

Question. You show a decrease in FY 1994 of 94 FTE in the Office of the General Counsel. Is this entire decrease the result of the transfer of legal functions to FDA? Were 94 FTE transferred from the Office of the Secretary to FDA?

Answer. No, the decrease in FTE for the Office of the General Counsel (OGC) between FY 1993 and FY 1994 is not due to the proposed transfer of OGC's Food and Drug Division to the FDA in FY 1995; for display purposes, all FDA-related resources have already been removed from the FY 1993 and FY 1994 figures shown in the Office of the Secretary (OS) Justification, in order to make the figures comparable to FY 1995 (see the explanations of comparable transfers on pages 6 and 9 of the Justification). The decrease is instead due to OGC's actual FTE usage in FY 1993 being higher than originally projected; therefore, a large decrease is now required in order for OGC to meet the Department's FY 1994 FTE target. No resources--either dollars or FTE--have been transferred from OS to the FDA yet; 34 FTE and \$2,745,000 are proposed to be transferred in FY 1995.

GENERAL DEPARTMENTAL MANAGEMENT

Question. The Administration has issued an Executive Order concerning Federal employment levels. The mandated reductions are to be completed by the end of FY 1995. Many of these reductions, we understand, are to be in headquarters personnel, yet you anticipate an increase of 4 FTE in the General Departmental Management (GDM) account for FY 1995. Please explain. You note in your justification that GDM staffing levels go down by 88 FTE between FY 1993 and FY 1995, but isn't this decrease primarily a result [of] the transfer of legal personnel to FDA?

Answer. You are referring to Executive Order 12839, "Reduction of 100,000 Federal Positions," issued February 10, 1993. This Executive Order mandates that not less than 4 percent of the Department's civilian FTE are to be eliminated by the end of FY 1995, and that at least 10 percent of this reduction is to come from the Senior Executive Service, GS-15 and GS-14 levels or equivalent. GDM is fully committed to meeting these targets.

As explained on page 54 of the OS Justification, the increase of 4 FTE in GDM in FY 1995 does not reflect new positions; instead, it reflects a redistribution of the approved OS FTE ceiling among the four OS appropriations. Also, the decrease of 88 FTE in GDM between FY 1993 and FY 1995 is not the result of the proposed transfer of legal functions from OGC to the FDA in FY 1995; all FDA-related resources have already been removed from the FY 1993 and FY 1994 figures shown in the OS Justification, in order to make the figures comparable to FY 1995. Instead, the decrease is due primarily to the actual FTE usage in FY 1993 being higher than was originally projected; therefore, a large FTE decrease is now required in order for OGC/GDM to meet the Department's FTE target levels for FY 1994 and FY 1995.

Question. What would be the impact of freezing the GDM account [at] the FY 1994 enacted level?

Answer. Freezing the GDM account at the FY 1994 enacted level would result in a reduction of \$3.649 million below the FY 1995 President's Budget, including \$3.020 million in salaries and benefits. The major impact of such a reduction would be felt in the staffing levels of the eight Staff Divisions which are funded through the GDM appropriation. A reduction of \$3.020 million in salaries and benefits equates to approximately 61 FTE. The most acute impact would be in the Office of the General Counsel, which comprises 41 percent of the GDM appropriation.

OFFICE OF INSPECTOR GENERAL

Question. What will be the impact of the proposed decrease in FTE for the Inspector General's office?

Answer. The Office of Inspector General (OIG) is taking innovative steps and implementing new methodologies to perform their work. These innovations, coupled with the setting of priorities and the deployment of staff in critical workload areas, will help OIG fulfill its mission and support the programs of this Department. Following are examples of steps being taken to assist OIG in using its limited resources to oversee the most critical HHS programs and issues.

- In areas with the fewest cases and the least amount of HHS dollars at risk, OIG investigative offices are being closed; by the end of FY 1994, ten investigative offices in nine States and Puerto Rico will be closed. OIG has shifted its investigations to those areas of the country which traditionally spend the most HHS dollars and where data indicates the most fraud cases occur.
- In OIG's Office of Audit Services and Office of Evaluation and Inspections, review processes are being refocused to minimize travel requirements and staff resources. OIG is developing joint Federal/ State audits in the health care area, to form a partnership with State auditors and/or State program evaluators to analyze issues which affect both the Medicare and Medicaid programs. Contract pre-award audit initiatives are also being developed, aimed at conserving audit resources while also providing the audit services needed at Medicare peer review organizations (PRO) and at colleges and universities.
- A recent OIG pilot study to test new ways to conduct PRO pre-award audits saved 68 staff days per audit, resulting in savings of \$29,920 per audit over traditional audit costs; the outcomes were similar to those using the traditional approach. This method will also be used for pre-award work at educational institutions and other entities, in order to reduce both costs and the number of staff needed without sacrificing audit quality.
- Finally, OIG is: reducing the number of middle management positions through attrition; improving products and processes through strategic planning efforts; and conducting joint work planning with other components within the Department.

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

Question. [What] is the distinction between the functions of the Office of the Assistant Secretary for Planning and Evaluation and the activities performed with funds appropriated for Policy Research? Are the FTE associated with [the] requested funding for Policy Research actually located in the Office of the Assistant Secretary for Planning and Evaluation?

Answer. The Assistant Secretary for Planning and Evaluation's GDM account contains funds only for staff salaries and expenses. The Policy Research account contains funds both for staff and for contracts and grants to carry out research and policy analysis. All FTE associated with the Policy Research account are located in the Office of the Assistant Secretary for Planning and Evaluation.

ADMINISTRATION FOR CHILDREN AND FAMILIES

Question. How is the Youth Gang Substance Abuse Program different from the Center for Substance Abuse Prevention's High Risk Youth Program?

Answer. The Youth Gang Drug Prevention Program, administered by the Administration for Children and Families (ACF), differs from the High Risk Youth Prevention Program, administered by SAMHSA's Center for Substance Abuse Prevention (CSAP), in that a) the Youth Gang program has a more specific target population, and b) its interventions are focused more on the basis of risk for associations with gangs, rather than on the specific basis of the risk for drug or other substance abusing behavior. In the Youth Gang program, targeted youth may or may not be directly involved in or at risk of drug abuse, depending on the nature and activities of the gangs in a grantee's community. The two programs are similar in that they share a common focus on youth.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. Secretary Shalala, the FY '95 budget appears to take a step backward from the low birth weight prevention initiative we begun last year. The budget freezes funding for the Healthy Start and Community and Migrant Health Centers programs, and cuts funding for the Maternal and Child Health Block Grant program. Since much of the problem in reducing low birth weight births is getting women to access early prenatal care, what justification is there for freezing funding for these programs which include outreach and education services for high risk women?

Answer. First, we need to be clear about the budget situation in FY 1995. This is essentially a zero sum game, if discretionary spending goes up in one program, we have committed ourselves to offset that increase somewhere else. With that as a parameter, most of our HHS programs were level funded in FY 1995, including Community and Migrant Health Centers, Healthy Start, and the State grant portion of the Maternal and Child Health Block Grant. However, if you examine overall HHS spending -- discretionary and entitlement -- funding for the prevention of infant mortality is approximately \$9.8 billion in FY 1995, \$847 million above FY 1994. In addition, let me remind you that the Public Health Initiative of the President's Health Security Act includes increases for capacity expansion and enabling services totaling \$4.5 billion from FY 1995 to FY 2000, of which \$600 million in total, \$100 million per year, is specifically designated for Community and Migrant Health Centers.

Question. It is my understanding that the most recent data on births among adolescents indicate that the teen birth rate in 1991 continued the rise that began in the late 1980's. Between 1986 and 1991, the rate of births to teens aged 15-19 rose 24 percent, from 50.2 to 62.1 births per 1,000 females aged 15-19. In your opinion, what is contributing to this increase in teen births?

Answer. The increase in the adolescent birth rate could result from either a decrease in the adolescent abortion rate or an increase in the adolescent pregnancy rate--or both. It is difficult to tell, at this point in time, which factor--or combination of factors is responsible. Data on adolescent births, through the vital registration system, are complete through 1991. However, because of the lag in reporting abortions, we have complete data only through 1988 and, as abortions are necessary to construct pregnancy rates, we have complete data on adolescent pregnancy only through 1988.

Question. The budget for FY '95 recommends an \$18 million increase for the Family Planning program. How do you propose utilizing this increase? Will these additional funds be targeted to areas with high teen and unwanted pregnancies?

Answer. The Title X Family Planning program is the primary point of contact for many teens into the health care system. The rising sexual activity rates among teens and concerns about unintended pregnancies and prevention of sexually transmitted diseases have increased the need to expand family planning services, particularly for low-income women and adolescents. The FY 1995 request of \$198.9 million is a \$18.0 million or a 10 percent increase over the FY 1994 appropriation. The proposed increase will provide funds to support: outreach to a side spectrum of persons not now receiving family planning services; increased focus on quality and completeness of services; more emphasis on prevention of teen pregnancy; expansion of current clinics sites and development of clinics in high need areas to provide services to an additional 300,000 clients; and more emphasis on training and retention, particularly minority practitioners.

Question. Why does your budget propose eliminating the adolescent and family life program? Will the new office of Adolescent Health continue to support pregnancy prevention programs targeted to adolescents which emphasize abstinence and parental involvement?

Answer. By transferring funding from the Adolescent Family Life (AFL) program, the Department is proposing to fund a broader range of adolescent health grant activities under an Office of Adolescent Health (OAH), as authorized in the Preventive Health Amendments of 1991. The problems of adolescents present a formidable public health challenge, and a more comprehensive and integrated set of health, educational, and social services are needed to protect and improve their health. In light of increasing rates of morbidity and mortality among adolescents, it is important that we develop and evaluate newer, more comprehensive approaches than have been possible under the AFL program.

While adolescent pregnancy prevention and care will continue to be a priority for the OAH, grants will be more broadly focused than they were under the AFL program. Under the new OAH, current or new grantees who propose to conduct adolescent pregnancy prevention projects using abstinence-based

curricula will be eligible to compete for funding under the new demonstration projects, but such abstinence education efforts will have to be part of more comprehensive project that includes a broader range of health, education, and social services for adolescents.

In addition, our HIV/AIDS prevention efforts, including especially our recently announced condom advertising campaign, will continue to emphasize that abstinence is still the only way to prevent HIV/AIDS transmission. Our youth need to know that the surest way to prevent AIDS is to refrain from having sex. This message is conveyed in several of our public service announcements (PSAs) which urge young men and women to "wait until the time is right." In addition to PSAs, we are working with communications experts to get AIDS prevention messages incorporated into prime-time television shows, and to saturate community-based media. We believe this approach will more actively promote youth sexual behavior changes.

Question. Last year, the Committee provided \$8.5 million to the Centers for Disease Control and Prevention's Comprehensive School Health program. I am advised that the program provides grants to states to promote activities at the State and local level which emphasize preventing: tobacco use, physical inactivity, and nutritional behaviors that result in chronic illness among youth, but does not include teen pregnancy prevention. Instead, teen pregnancy prevention education is tied into AIDS prevention and education curriculum. What is the rationale for limiting the scope of the comprehensive program? Would you not agree that any comprehensive health program targeted to youth should include information concerning the health effects of teen pregnancy and early prenatal care?

Answer. I do not believe we should view the CDC Comprehensive School Health program as having limited scope by not making teen pregnancy prevention a primary focus. While nutrition, physical exercise and prevention of tobacco use are key elements, any good school health education program must direct attention to reproductive health. Schools are addressing this topic more and more and, in a variety of ways, CDC's efforts will compliment this heightened attention to teen health.

Question. Would you support setting aside funds within the comprehensive school health program in FY '95 for grants to local health departments and education agencies to demonstrate effective models for teen pregnancy prevention programs in the schools?

Answer. Preventing teen pregnancy is a high priority of this Administration and the Surgeon General has made this one of the most critical items on her agenda. The FY 1995 budget request includes \$7 million for a new PHS Office of Adolescent Health which will focus on a broad range of teen health topics, including unintended pregnancy. Since the funding for this new office comes from the former Adolescent Family Life grant program, we would expect a strong continuing emphasis on preventing teen pregnancies by this office. In addition, the FY 1995 request includes an increase of \$98 million over FY 1994 for family planning services, both Medicaid and PHS Title X, which are available to teens.

For now, we believe that the CDC Comprehensive School Health program should maintain the same level of effort as in FY 1994 to promote healthy nutrition, physical exercise, and prevention of tobacco use.

Question. What other existing programs within the Department of Health and Human Services can you identify that could be increased to address the teen pregnancy issue? Should the Administration and the Congress begin new programs to focus on reducing unintended teen pregnancy?

Answer. Teen pregnancy is being addressed in a variety of new ways by the Department. The Public Health Initiative in the President's Health Security Act includes over \$1.8 billion over six years for school-based health programs. This includes \$1.5 billion to provide health services to students in schools with a high portion of low-income students and \$50 million annually for a school education program for students in grades K-12. Reproductive health will be a part of these school-based health programs. Also, as part of the President's welfare reform, we will be focusing attention on better ways to prevent teen pregnancy and promote parental responsibility.

Question. What coordination exists between the Department of Health and Human Services and the Department of Education with regard to programs focused on reducing the rate of teen births?

Answer. The key element in health promotion is education. Our efforts to design disease prevention and health promotion strategies for adolescents, including prevention of pregnancy, have been developed in close collaboration with our colleagues in the Department of Education. In particular, the President's Health Security Act includes an extremely important initiative to begin providing school-aged children, grades K-12, with the comprehensive

health education necessary to enable them to remain healthy. Sequential, age-appropriate health education, including information on human sexuality, would provide children with the knowledge they need to assure that they can make responsible decisions about whether to be sexually active, and how to avoid pregnancy as well as sexually transmitted diseases. Health services, including contraceptive services, are logical complements to comprehensive health education which can provide needed health services as well as increase access to other needed health care.

Currently, the Centers for Disease Control and Prevention (CDC) provides financial and technical support to every State and 16 local education agencies, as well as 23 national organizations to provide effective health education to benefit children. In managing this school health initiative, CDC works closely with the Department of Education's Office of Elementary and Secondary Education.

Question. Secretary Shalala, teenage pregnancy, birth and abortion rates in the US are the highest in the Western world, but teen birth rates have fallen dramatically since 1970 in much of western Europe. For example, the United Kingdom has decreased its birth rate to teens from 49.1 percent in 1970 to 31.7 percent in 1989, while Japan's birth rate to teens has remained at a rate of approximately 3.7 percent since 1970. Are their programs that have been implemented in the Western European countries that can be duplicated here in the US? Can you explain the reason for the low birth rate among teens in Japan?

Answer. High adolescent birth rates in the U.S., as compared to those of Western European adolescents, cannot be attributed to differential rates of abortion or sexual activity. Abortion rates are substantially lower in Western Europe and levels of adolescent sexual activity are similar to those in the U.S.

Contraceptive use among Western European adolescents, however, is higher than among adolescents in the U.S. In addition, the use of more effective methods, in particular oral contraceptives, is higher in Western European countries than in the U.S.

In Western Europe, the governments are the principal funders and providers of health services. In addition, governments have recognized the need for adolescent contraceptive services and have acted accordingly. Contraceptive services tend to be more accessible to adolescents in Western European countries, as well as confidential and low cost. In some cases, there are clinics set up specifically for adolescents and young adults.

While comprehensive sexuality education in Western European schools is not universal, the mass media, either controlled by or in cooperation with government, has widely disseminated information about contraception and responsible sexual practices. These programs can be implemented, at least to some extent, in the U.S. There is every reason to believe that comprehensive health education--including sexuality education and access to contraceptive information and services for adolescents who need them will reduce our disturbingly high rates of adolescent pregnancy and childbearing.

Question. In 1990, an estimated 51 percent of Aid to Families with Dependent Children (AFDC) payments went to recipients who were 19 or younger when they first became mothers. Based on estimates of AFDC, Medicaid and Food Stamps support to families begun by a teen birth, teenage parenting cost the U.S. over \$25 billion in 1990, an increase of 16 percent or \$3.5 billion over 1989. According to the Population Resource Center, it is estimated that if every teen birth had been delayed until the mother was in her 20's, the U.S. would have saved 40 percent of these expenditures, or \$10.2 billion. As the Administration and the Congress works toward revamping this nation's health care system, and the enormous task of finding ways to finance the coverage of those 37 million Americans without health insurance, I would think investing in programs that could reduce the costs associated with teen pregnancy is one way to save an enormous amount of money. What specific proposals will the Administration recommend to address this issue when the welfare reform plan is submitted to Congress?

Answer. The problem of teen pregnancy is being examined in the context of the President's welfare reform. A major factor in welfare dependency is that young people are having children before both parents are ready to assume the responsibility of raising children. Unwed mothers accounted for about four-fifths of the growth of 1.1 million in the welfare rolls over the past ten years, from 3.86 million families in 1983 to 4.97 million families in 1993. As

part of the President's welfare reform, we will be focusing attention on ways to prevent teen pregnancy and promote parental responsibility.

Question. In addition to the increase in teen pregnancy, births to unmarried women aged 20-24 have also risen dramatically over the past 30 years, increasing from 39.7 percent in 1960 to 68 percent in 1991 (the most recent data available). What programs are in place within the Department of Health and Human Services that address the issue of unintended pregnancies for women aged 20-24?

Answer. A number of HHS programs provide services that focus on unintended pregnancy. Federal support for family planning services necessary to avoid pregnancy comes from several sources: (a) the Title X national family planning program which provides grants to support the provision of family planning services to 4.3 million women annually, of whom about 1/3 are ages 20-24; (b) the Social Services and Maternal and Child Health Block Grants which support family planning as a part of the health and social services provided by their grantees; (c) the Medicaid program under which family planning is a mandated service; and (d) the Healthy Start program which provides health and social services to women including women with unintended pregnancies. The Title X national family planning grant program provides contraceptive services to predominately low-income women at no cost or a moderate fee in order to assist women with the timing and spacing of their children. Medicaid, the Social Services Block Grant and the Maternal and Child Health Block Grant also fund supportive health and social services, including prenatal care services for women with unintended pregnancies.

The National Institute of Child Health and Human Development's contraceptive development program supports clinical trials and laboratory studies aimed at developing and improving methods of fertility regulation for both men and women that are safe, effective, reversible, and acceptable to various population groups.

Finally, through the research and survey activities of the National Institutes of Health and the Centers for Disease Control and Prevention, the Department also collects and analyzes information about pregnancy, birth, abortion and sexual activity in order to enable planners and administrators to better focus their efforts to provide high quality reproductive health care to the population most in need of these services.

Question. Recent reports suggest that savings could be achieved in our health care system if patients better understood their rights under state law to develop 'living wills' and/or issue advance directives. Monday's issue of *USA Today*, included an article on the findings of a study conducted at Thomas Jefferson University which found that advance directives not only preserved patient autonomy, but can achieve "huge savings." Yet fewer than 15 percent of Americans have completed advance directives. Last year, the Committee set aside \$1 million within the Health Care Financing Administration's research and demonstration account to develop demonstration projects to inform patients of their rights under state law to self-determination. What action has been taken to implement this directive? Would you support issuing a separate RFP for demonstration projects in this area? Does your FY '95 budget request include funds to expand our knowledge of how better to inform patients and providers about their rights to self-determination?

Answer. HCFA has budgeted \$4 million for its FY 1994 general grants solicitation. The solicitation expresses interest in proposals that implement counseling programs for patients and providers that improve understanding of patients' rights to decline medical treatment and or to formulate advance directives (living wills).

We will consider issuing a separate grant solicitation if we do not receive proposals that are technically sufficient through the general grant solicitation.

Our FY 1995 budget provides for the continuation of FY 1994 grant awards.

Question. What are your plans regarding the proposed Information Counseling and Assistance (ICA) grants? Have any of these funds been used to provide information to Medicare and Medicaid beneficiaries regarding their rights to self-determination under state law? If not, could they?

Answer. Counseling on patient self-determination has and will continue to be part of the ICA program. We have developed and distributed to all states a video and pamphlet on patient self-determination and advance directives. We have also included this issue in the training manual for counselors. Counselors are trained to respond to questions about advance directives as well as routinely discuss these issues when counseling beneficiaries with regard to hospital admissions.

Question. The Administration's budget requests an increase of \$700 million for the Head Start program, and while I agree that Head Start program is an excellent program which addresses not only the education needs of

children but also the social services needs of their families. However, the increase is at the expense of many other programs such as LIHEAP which also provides much needed heating services. If the Congress approves your FY '95 budget request for Head Start, we would have increased the program over \$2 billion since 1992. Could an increase of this magnitude be used efficiently? Please provide for the record a breakdown of how the increase was used in FY '93, and FY '94, and how your FY '95 budget request would be spent.

Answer. Yes, in fact I believe such an increase is critical to strengthening quality in all aspects of the program; ensuring strategic expansion of services; and, providing local flexibility to respond to family and community needs. The following table, provided for entry in the record, provides a breakdown of actual increased Head Start spending in FY 93, and proposed spending in FY 1994 and FY 1995.

HEAD START
Allocation of Appropriations Increases FY 1993-1995*

Increase in Head Start Funding (BA in Millions)	FY 1993 Actual	FY 1994 Enacted	FY 1995 Estimate
Cost of Living Adjustment	\$62	\$71	\$87
Quality Increase	128	119	152
Training and Technical Assistance	11	11	14
Research, Demonstration & Evaluation	.4	3	--
Monitoring/ Review	1	2	--
Expansion **	372	344	447
Total Increase - Head Start	\$574.4	\$550	\$700

*Incremental increase over the previous year appropriation.

**In FY 1994 and FY 1995, increased funding provided to grantees permits them to expand services to unserved children, expand service levels to full year/ full day, and/or increase the quality of service provided in local programs.

Question. Head Start is successful because it is a comprehensive program responding not only to the educational needs of children but also to the social services needs of their families. Head Start staff have expressed concern over the growing number of multi-problem families enrolling in the program. Given the growing drug problem in this country, are Head Start staff adequately trained to deal with this problem? Shouldn't there be more emphasis on training in the areas of drug counseling and education for Head Start parents?

Answer. Head Start has taken a number of steps to help local programs deal with issues of substance abuse in families of Head Start children. As a part of the Head Start National Substance Abuse Initiative, the Department began funding a number of substance abuse prevention grants in FY 1991. From what was learned in those settings ACF published the Head Start substance abuse guide, which has been available to all grantees for 2 years now. This guide provides excellent resource material to help local programs develop training on substance abuse as it relates to Head Start Families. In addition, ACF has been piloting a curriculum on substance abuse for 66 Head Start Family Service Centers, 106 Parent Child Centers, and the 40 Grantees who received special substance abuse prevention grants. In the near future we will make this curriculum available to all grantees.

Question. Studies of Head Start have shown benefits for disadvantaged children participating in the program, but some of the early gains have been lost once they enter elementary school. Some of the important benefits of Head Start which include addressing the needs of the entire family, such as parenting education and access to a wide range of social services for the parents, are generally not available to disadvantaged children once they enter public schools. What are the Departments of Health and Human Services and Education doing to ensure that disadvantaged children continue to receive the type of parenting education and social services support that they need in public schools to sustain early educational gains achieved through Head Start?

Answer. As a part of Head Start reauthorization the Head Start Transition Projects are continued and the Budget contains \$20 million for this purpose in FY 1995. The reauthorization also strengthens provisions to improve communication and coordination between Head Start programs and Local

Educational Agencies and encourages ongoing parental involvement once Head Start children enter schools. The Department of Education has requested a \$660 million increase in Title I Grants to Local Educational Agencies (LEAs) and to implement more comprehensive approaches in the early elementary school years which will help low income children sustain the gains made through Head Start. In addition HHS is working with the Department of Education through an Interagency agreement to field test a process for parents, LEAs, and community organizations to implement more comprehensive services for young children in the primary grades.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

Question. How much of the \$888 million for childhood immunization -- \$464 million for the childhood immunization program at CDC and \$424 million for a new vaccines entitlement program -- will be used to purchase vaccines for children? How many children will be provided federally purchased vaccine, and what percentage of the child population will be served by the federal programs?

Answer. The FY 1995 Childhood Immunization budget request of \$888 million includes \$502 million to purchase vaccines -- \$422 million through the new *Vaccines for Children* entitlement program and \$80 million through the CDC discretionary appropriation. We believe that 73% of children in the U.S. will be eligible for Federally purchased vaccine through the *Vaccines for Children* entitlement and public health clinics. Translated into numbers of children, this would be approximately 16.4 million who are eligible to receive recommended vaccines.

Question. According to the most recent data released by CDC, immunization rates for two-year-olds in 1992 were above 80%, compared to the 50% rates that were quoted only months ago. In light of these rates, would an approach targeted at the chronically underimmunized be more effective than the broad-based vaccine purchase plan you propose?

Answer. The *Vaccines for Children* entitlement program does target chronically underimmunized children. These are kids whose parents cannot afford to immunize their children -- parents in poverty and likely members of racial or ethnic minorities. In addition, we expect the new *Vaccines for Children* entitlement to reduce the burden on the public sector because less kids will be referred out of physicians' offices to public health clinics. This should permit public health clinics to target harder to reach kids.

Question. As you know, discretionary funds appropriated under the Section 317 program cannot be used for excise taxes or shipping and handling associated with the new entitlement program. How much do you estimate direct delivery of vaccine under the entitlement will cost? Where will the funds for delivery come from? If the Department believes it has statutory authority for expenditures for shipping and excise taxes for the new entitlement program, please cite provisions in the statute.

Answer. We expect shipping of vaccine under the new entitlement to cost \$33 million in FY 1995 -- \$20 million for States to ship vaccine and \$13 million for a warehouse for Federal distribution where States do not choose to ship vaccines themselves. We believe the Social Security Act authorizes payment of these shipping costs with Title XIX funds under Section 1928(a)(2)(A). Authority to pay excise taxes is contained in Section 1928(d)(3)(B) which refers to contracts in place as of May 1, 1993. These contracts had provisions to pay excise taxes, albeit that the authority for collecting excise taxes had expired at that time.

Question. In light of reports that vaccine is wasted in some states because of poor inventory control and that some states have purchased more vaccine than necessary to immunize their entire child population, what procedures have you implemented to monitor supplies of vaccines to the states and prevent wastage of vaccines? Have you implemented any sort of audit system to ensure that the states are accountable for the vaccine they receive?

Answer. We are talking to States right now about how best to manage the stock and flow of vaccine, including inventory reporting systems. We are doing this mindful of the need to use precious resources for immunizing children, rather than setting up burdensome and expensive administrative systems. When we have agreed upon a system for monitoring the vaccine supply, we will be happy to share the details with the Committee.

Question. Have you implemented any maintenance of effort requirement to ensure that the states continue their financial support for childhood immunization, including support for vaccine delivery activities?

Answer. We are aware that the Conferees expected States to maintain the same level of effort on childhood immunization in place at the time of

enactment of the Omnibus Budget Reconciliation Act of 1993. However, CDC does not believe it has legal authority to require that States maintain a previous level of effort, nor to monitor State levels of effort. Nevertheless, CDC is asking States to justify any reductions in their requests to CDC to purchase vaccine in FY 1995 under the optional use clause (where States buy vaccine themselves at the Federal price), compared to FY 1994.

Question. DHHS has published the "Requests for Proposals" for vaccine for the new Vaccines for Children Program, and the projected public sector purchase of vaccines exceeds the total volume of vaccine needed to immunize every child in the U.S. As an example, last year the federal public purchase of MMR was around 7.1 million doses. The Department's RFP, released several weeks ago, calls for a purchase of 27 million doses for an 18-month period. Even taking into account the expanded contract period, and the newly-eligible population, a four-fold increase appears extreme. Under what circumstances would the Department purchase 27 million doses over an 18-month period? Please provide the underlying justification for the vaccine purchase projections for all antigens, including acellular DTP?

Answer. CDC is reexamining its solicitations in general, and in particular the following items: minimum guaranteed and maximum quantities of vaccine by antigen; multiple awards; and optimal length for contracts.

With regard to vaccine purchase projections, CDC projected the need for vaccine for all eligible children (primary birth cohorts and "catch-up" of 3 to 18 year-olds). In addition, CDC factored in a large initial investment to supply providers with 3 months of stock; to place 2 months in storage; to supply vaccine for outbreak control; and to maintain a stockpile. CDC is currently reevaluating these projections, particularly the optimal level desirable for the stockpile.

Question. The Congressional Budget Office estimates of the cost of the Vaccines for Children Program were based on an eligible population that is defined in that statute. Children who are eligible to receive federally purchased vaccine include Medicaid eligibles, the uninsured, and the underinsured who receive their vaccines at federally qualified health centers. Can you explain how you can purchase vaccines for more children than are included in the birth cohort and remain within the budget estimates for the program?

Answer. The President's Budget for FY 1995 includes funds to purchase vaccines for children who are out of compliance with the Advisory Committee on Immunization Practices (ACIP) recommended vaccine series -- otherwise referred to as the "catch up" population. After a few years, the need to do "catch up" immunizations will go away. Our current estimates were developed by States and include both kids getting shots on the regular ACIP schedule and kids getting "catch-up" doses of vaccine.

Question. Please provide to the committee both the survey and the survey results conducted to determine the number of doses of vaccine necessary for: Vaccines for Children, the 317 program, and state optional purchase.

Answer. We are transmitting these materials to the Committee under separate cover since they are so voluminous.

Question. DHHS intends to expand the vaccine stockpile from a 3- to a 6-month supply. This could represent a substantial increase in storage space requirements as well as problems related to rotating such a large volume of stock. How does the Department plan to handle this? What is the estimated cost (beyond the cost of vaccine purchase) of expanding the stockpile? Which funds will be used by the Department to pay for the new administrative expenses associated with the expanded stockpile?

Answer. The CDC has almost always maintained a 6-month stockpile of vaccines. Recently, however, when vaccine manufacturers were having difficulty with FDA approval of certain DTP lots, CDC was asked by manufacturers to draw down the DTP stockpile to a 3-month supply. There is no plan to build up the stockpile this year because manufacturers are presently working on new combinations of antigens. CDC will not stockpile vaccine that may become obsolete next year.

Question. DHHS is in the process of exploring ways to designate state health departments and private physicians as federally qualified health centers for the purpose of administering the Vaccines for Children program. Notwithstanding any legal or regulatory barriers, how would such a change in designation expand the current entitlement? By how much would such a redesignation increase the cost of the entitlement?

Answer. Earlier, CDC explored the possibility of designating certain providers as Federally Qualified Health Centers (FQHCs) for the sole purpose of immunization. CDC has decided not to pursue a national waiver for this purpose, but States are free to independently seek this authority for participating health clinics, if they choose. Any estimate of cost would depend on choices States would make.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Question. The Subcommittee is in a particularly tough position this year, given the tight discretionary caps we have had the fiscal discipline to impose on the appropriations process. We now have to find out if the particular way the Administration proposes to take care of children and low-income Americans through this Department makes sense. Are the right things increased, and are the right things trimmed to pay for those increases?

Let me start by saying that I am generally pleased by the sorts of things the Administration proposes to increase: Head Start, Ryan White AIDS Treatment, and Childhood Immunizations. However, I can not support such increases if they have to come at the expense of cutting LIHEAP, which provides over 130,000 households in Wisconsin alone with assistance in heating their homes. With winters like the one we just had, we know we need to continue this program -- NOT cut it in half. Secretary Shalala, I would like to pose several questions about this proposal:

Did you examine alternative ways of finding the \$707 million you cut from LIHEAP? What were the alternatives? Why was LIHEAP chosen instead?

Answer. In order to fund priority investments while remaining within the discretionary budget caps, the Administration reduced funding for a number of programs including LIHEAP. The LIHEAP program was originally set up to help low income families deal with the drastically increased home energy costs that resulted from the late 70's era oil embargo. Due to reductions in overall energy prices (after adjusting for inflation) and the related decrease in the home energy burden on low income families, we believe this is the appropriate time to reduce LIHEAP funding. Our investment increases did not come without a price. As I said in my testimony, we were able to finance them only by looking very critically at our base and finding a reasonable path for those programs as well. Our investments in Head Start, SAMHSA, and NIH are deliberate, focused efforts to increase funding for our highest priorities. They should not be sacrificed.

One of the Administration's justifications for cutting LIHEAP was that welfare reform will create a better way to take care of the low-income people kept warm through LIHEAP. We understand you will eventually produce a welfare reform plan, but if it is not acted upon by Congress this year, as seems likely, won't that leave people formerly served by LIHEAP high and dry?

Answer. Your question gets at the heart of this issue. Should we continue the past practice of narrowly targeted programs that address one specific need, or should we look more broadly, more comprehensively at the financial assistance we provide low income families. I believe that to the extent that home energy problems are ongoing income problems, they are best addressed by programs aimed at overall economic self-sufficiency. And, as I have said before, the Administration is addressing these problems through health care reform, through the expanded Earned Income Tax Credit (EITC) for the working poor and through welfare reform for those who receive public assistance. The EITC in particular is a valuable mechanism for increasing the financial resources available to the working poor for many purposes, including home energy costs. The significant increase in the EITC last year allows us to move toward a less narrow view. At the same time, our reauthorization proposal for LIHEAP gives States a greater incentive to leverage Federal dollars and obtain non-Federal energy assistance, and the flexibility to target LIHEAP funds on those low income households with the greatest energy burden and continued emergency authority so that we will be able to respond to energy related crises.

What sort of an across-the-board reduction in HHS discretionary programs would be required to make up for this cut? Given the importance of LIHEAP, isn't this a feasible alternative?

Answer. A two percent across-the-board reduction in the \$35.4 billion budget authority requested by HHS would achieve \$708 million in savings. However, rather than making blind, across-the-board reductions, we looked critically at funding levels for each individual program within our base to find what we consider a reasonable path for those programs.

Question. I notice that most HHS programs will just keep on receiving the same amount as they did in FY94. You propose a few increases, a very few big decreases, like the one in LIHEAP, and leave everything else steady-state. This doesn't seem right. Are you telling me that the hundreds of programs you are continuing are all better than LIHEAP? That they couldn't all be, perhaps, sliced a bit to be able to afford the increases you propose? We're all in a tough spot -- we have to be careful with the public's money. I have reduced the size of my own staff to save money; I think everyone should be able to. I would be interested in knowing how much it would save if you reduced by 2% each of the programs you are straight-lining?

Answer. An across-the-board reduction of 2 percent applied to all programs frozen at FY 1994 levels would yield savings of approximately \$93 million.

Question. I see you have proposed a slight reduction in curriculum assistance grants to health professionals. In a time when we have to make tough choices, this may make some sense. Tell me, how much assistance in physician and other health profession training does the Federal government already provide through Medicare? Isn't it over \$5 billion? And for people whose average income can be four or five times the median income of people in Wisconsin? While I recognize there are some reasons to help subsidize some health professions training, we don't help any other profession get training this way -- lawyers pick up their own costs, as do MBA's and accountants. If we're proposing big cuts in LIHEAP, which goes to poor people, it seems like cuts in our subsidies to highly-paid professionals could have been made a bit bigger. Do you agree?

Answer. In Fiscal Year 1994 the Medicare program will spend over \$5.7 billion on graduate medical education. And, as I mentioned earlier, we looked critically at funding levels for each individual program within our base to find what we consider a reasonable path for those programs.

Question. As you may know, the GAO has estimated that up to 10% of health care spending goes down the tubes as a result of fraud and abuse.

As we struggle to restrain the health care cost spiral, should the Federal government be doing more than we are doing today to combat health care fraud?

Answer. Health care fraud, abuse, and waste are major problems that cost our nation's health care system billions of dollars each year. In addition, they put citizens at risk by exposing them to unnecessary or substandard medical tests, procedures, or equipment. It will take the concerted efforts of Federal, State, and local officials to deal with these problems effectively. This Department is committed to eliminating fraud and abuse in the health care area and is targeting resources to ensure that such practices are reduced.

In the Medicare program, the Health Care Financing Administration (HCFA) is concentrating its efforts (1) to identify and target aberrancies and potential areas of abuse and over-utilization through pattern analysis and focused review and (2) to educate health care providers to submit claims and billings correctly. Through this new focus, HCFA expects to recover more overpayments and to deter more incorrect billings and claims submissions utilizing fewer resources. HCFA expects a combined \$244.3 million increase in savings from Medical Review/Utilization Review and Provider Audit activities in FY 1995 with a \$4.2 million smaller investment. Through its matching funds for State Medicaid Fraud Control Units (MFCUs), HCFA and the States recover substantial savings from fraud and abuse in the Medicaid program. Passage of the President's Health Security Act (HSA) will more thoroughly address the issue of health care fraud and abuse in the private sector through its quality management and fraud and abuse provisions.

Lack of resources to identify waste and combat fraud and abuse is a major problem because it allows harmful practices to continue and defrauders and abusers to escape detection. Therefore, we support the establishment of an All-Payer Health Care Fraud and Abuse Control Account as proposed in the Administration's Health Security Act. Funds to be deposited in this account would include criminal fines imposed in cases involving a Federal health care offense, civil penalties and damages imposed in health care cases under the False Claims Act (other than funds awarded to a relator or for restitution), administrative penalties and assessments in health care cases (other than funds returned to original payers, such as the Medicare Trust Fund or the States), and amounts resulting from the forfeiture of property by reason of a Federal health care offense.

I'm concerned that many of our current fraud laws are limited to Medicare and Medicaid fraud. This leaves unscrupulous providers to prey on the private health payers without the threat of significant Federal sanctions. Shouldn't the Federal government be concerned about health fraud and abuse wherever it occurs, since cost-shifting means that we all end up paying for it? I will introduce bills tomorrow that will, among other things, extend Federal jurisdiction to punish health fraud and abuse that occurs in the private sector. Does this sound like a good idea?

Answer. Under the HSA, the Departments of Health and Human Services and Justice will be principally responsible for coordinating all applicable law enforcement agencies in the prevention, detection, and control of health care fraud and abuse nationwide through investigations, audits, and similar activities. Passage of this legislation will extend Federal jurisdiction to punish health fraud and abuse occurring in the private sector.

The Inspector General in your department has been quite effective at prosecuting unscrupulous providers and recovering taxpayer dollars these providers have ripped off. I understand that they have actually recovered four dollars for each dollar we invest in health care fraud investigations. I am troubled that your proposed FY95 budget does not increase the budget for health fraud investigators. Can you explain why not?

Answer. Discretionary budget limitations and finite resources force us to make difficult decisions in allocating scarce funds. We are responding to that challenge by utilizing these limited resources more effectively through greater coordination among agencies and improved agency practices. HCFA and the OIG have increased their cooperation in the area of health care fraud and abuse by combining their efforts in the area of civil monetary penalties and rooting out fraud and abuse in the Medicare and Medicaid programs.

In FY 1993 OIG investigations, audits, and evaluations resulted in recoveries and savings to the U.S. Government of \$61 for each OIG budget dollar appropriated or \$4.6 million in savings per OIG FTE. This is consistent with the OIG dollar savings over the years.

Question. In total, HHS' 1995 staffing levels are consistent with the National Performance Review and Presidential Executive Orders. However, it seems strange to me that within this total you plan to increase middle management while cutting some line staff -- the people who get the job done. As a businessman, I don't understand the logic. Could you comment on the proposal to increase the staff of the Assistant Secretary for Health's office by 3% over FY94 while staffing levels are reduced in NIH, CDC, IHS, and other health agencies?

Answer. Staffing levels for the Office of the Assistant Secretary for Health (OASH) are proposed to be 1,145 FTE in 1994 and 1,181 FTE in 1995.

This increase is due in large part to the transfer to OASH of 54 FTE involved in accounting activities from the Office of the Secretary Working Capital Fund. This transfer was not accounted for in the FY 1994 staffing targets.

Partially offsetting this is a decrease of 18 FTE in OASH in FY 1995 due to general administrative savings. This includes 4 FTEs in direct OASH programs, which will save approximately \$240,000 in FY 1995; 8 FTEs in OASH reimbursable activities; and 6 FTEs in reimbursable PHS Service and Supply Fund activities accounted for in the OASH staffing ceiling.

Question. If we are able to pass legislation enacting universal health coverage, to be phased in over some period of time, can we expect to free up resources that now go to Public Health Service grantees so we can fund other priorities within this subcommittee's jurisdiction?

Answer. Under the Health Security Act, all Americans and legal residents will have health insurance coverage for the comprehensive benefit package. As a result, many of the personal health services currently provided by PHS programs for the uninsured will be covered and paid for within the new system. PHS programs that subsidize the delivery of health care services will not lose funding as the result of health care reform. However, the funding streams will change. Once health care reform is fully implemented, insurance revenues will be the source of funding for services contained in the basic benefit package. Federal grant funds may be reduced to the extent that those grant funds now subsidize such services.

Question. I was disappointed to see that the Administration chose to request more budget authority than it had outlays to pay for under the discretionary caps -- and chose to use an accounting gimmick called "delayed obligations" to make up the difference:

Is this an honest way to do budgeting?

Answer. Yes. Delayed obligations allow us to fund more of our priority programs without being constrained by current year outlays.

Won't it put us in a bigger bind next year?

Answer. The Administration's 1995 budget is a multi-year spending plan which includes the effects of delayed obligations in the "out-years." Enactment of the President's Budget, as requested, will not create additional outlay problems in succeeding years.

Why didn't the Administration reduce its proposed increases to live within the money available rather than resort to this accounting device?

Answer. Delayed obligations allow us to maximize our use of current year resources. We were able to provide over \$100 million in additionally budget

authority in 1995 because of delayed obligations. We consider the additional \$100 million paramount to the Administration's overall investment policy, thus worth the outlay burden in the outyears.

Question. Last year, the Congress created a new entitlement to ensure that kids get their shots. Have vaccines begun to be distributed to the states under this new program?

Answer. We are presently finalizing the details of how vaccine will be distributed and engaged in contract negotiations with vaccine manufacturers. Based on our progress so far, we expect to have a sufficient supply of vaccine in the hands of physicians and clinics by October 1, 1994, the first day the new *Vaccines for Children* entitlement benefit takes effect.

Question. The Administration has made some reductions in various departments to reduce overhead in Federal staff. This year's budget proposes an analogous reduction in overhead payments made to colleges and universities which conduct research. How much does the department spend on overhead at non-research organizations, such as health clinics, education groups, state health departments, etc.? Please break out by type of grantee and PHS agency. Have you thought of limiting overhead in these areas, as you have begun to do internally and with research universities?

Answer. We have not proposed any across-the-board policy changes which would "limit" payments for overhead, or indirect costs, for non-research grantees. Of course, payments to different categories of grantees -- hospitals, state and local governments, non-profit organizations, for example -- are already governed and limited by definition in various OMB cost principle issuances, and by negotiation by the HHS Division of Cost Allocation. However, specific data on indirect costs for non-research organizations is not routinely collected. In addition, administrative payments to many of our grantees are already limited by statute. Administrative costs for Head Start grantees, for example, are limited to 15% of the total grant amount.

Indirect cost payments to universities conducting Federally-sponsored research have been scrutinized, and limited in response to reported abuses by universities, and unacceptable escalation in the amount of research grant funds reimbursing indirect costs.

Question. You have proposed a large increase for Head Start, \$700 million. However, I am having a hard time figuring out why we would make such a big increase if it would only allow a few thousand more children to be served. I thought the priority was getting more kids into Head Start, and I find that you're planning to spend most of the increase on other things. Could you tell me how many additional children you could serve if the entire \$700 million was applied to expanding the program? What portion of the \$700 million is just for expansion? What would happen if that was as big an increase as Congress could afford?

Answer. On June 16, 1993 I called together a bipartisan Advisory Committee on Head Start Quality and Expansion to review the Head Start program and to make recommendations for improvements and expansion. Their final report entitled "Creating a 21st Century Head Start" provides the basis for our investment in Head Start Quality and Expansion. The advisory committee recommended that quality of services be the first priority. Next, the advisory committee recommended that Head Start expand services by reaching out to children and families currently unserved, promoting full day and full year programs that are necessary to support parents who work or are involved in training programs, and improving services to families with younger children. Also, we are giving local programs the ability to target increases to meet the needs of their communities. Current law requires that we spend at least 25% of any increase in Head Start funding on cost of living adjustments and quality improvements so it would be impossible for us to spend the entire \$700 million on expansion.

Question. I notice that the National Health Service Corps continues at last year's level. Tell me, isn't the NHSC merely a stop-gap -- don't most of the physicians in whom we have invested a medical education leave their post after 2-3 years, creating yet another slot that needs filling? If we really want to get physicians and other health professionals to serve in rural and inner-city clinics shouldn't we work to increase the financial rewards for primary care physicians, so that once people are attracted to a site they are more likely to stay there -- instead of creating a bureaucracy to fill up slots that we know will just need re-filling?

Answer. The mission of the National Health Service Corps (NHSC) is to assist in the development, recruitment, and retention of community-responsive, culturally competent, primary care providers to serve people in officially designated health professional shortage areas (HPSAs). The ultimate success of the NHSC recruitment and retention efforts would be a decrease in the ratio of health care providers to patients, and the decrease in the distance or required

travel-time between providers to a level sufficient enough to eliminate all of the Nation's HPSAs.

An increase in the financial rewards for primary care providers is one of the factors which could positively affect recruitment and retention for rural and inner-city areas. However, our research has shown that providers list many additional reasons for making their career decisions. Factors such as adequate orientation, continual and appropriate nurturing and contact from a professional network, family needs, feeling appreciated by patients and the community, feeling as if a part of a bigger organization, respect, and recognition are often given. Since these factors have been identified, the program has given increased emphasis to the concerns of providers.

Record numbers of new providers were recruited last year which points toward significant progress. However, until all shortage areas are eliminated, the NHSC is committed to serving where others have chosen not to go.

QUESTIONS SUBMITTED BY SENATOR MARK HATFIELD

Question. Ms. Secretary, I am concerned about the budget request for rural health programs. The budget freezes the Community and Migrant Health Centers, Rural Health Outreach Grants and the National Health Service Corps which have served rural Oregon well during very difficult economic times. In addition, the budget proposes consolidating nine primary care health professions programs with one of the most effective programs serving rural Oregon, the Area Health Education Centers program. As a result of this consolidation, do you intend to eliminate funding for the existing AHEC grantees in FY 95? What justification is there for the Committee consolidating funding for these programs absent action by the authorizing committee? How much savings do you project from consolidation of these programs?

Answer. Our FY 1995 request for consolidation in the health professions programs will not eliminate the Area Health Education Centers (AHEC) program. We are proposing to consolidate the AHEC program with other Title VII and VIII primary care programs to reduce administrative burdens on educational institutions and the Federal government while increasing flexibility. The program will be continued simply in the larger context of primary care. We will work toward achieving this goal through consultation with the authorizing committees over the next two years. We project to save approximately 25 FTE through the health professions consolidations. Regarding the straight-lining of Community and Migrant Health Centers and the National Health Service Corps, let me just say that additional funds are excluded for the important activities within the Public Health initiative embedded in the Health Security Act.

Question. Ms. Secretary, your budget recommends increases in worthy areas such as Head Start, medical research, substance abuse treatment and AIDS services. I fear, however, that the viability of these increases is questionable in light of the cuts proposed in other areas? In addition to the \$707 million cut in the Low Income Home Energy Assistance Program, cuts in programs in other Subcommittee's will place great pressure on the Committee. For example, the proposed cuts in the Indian Health Service, which is within your Department's jurisdiction but is funded in the Interior bill reflect no increase for population growth or medical inflation, and no funding for sanitation facilities or hospital and clinic construction. How can HHS possibly meet its ongoing program requirements under this proposal.

Answer. We are committed to meeting the health care needs of American Indians and Alaska Natives. Our FY 1995 budget request of \$1.85 billion for health services represents a 2 percent spending increase. At a time when the budgets of many government programs are being cut, or held at last year's level, this increase is important. As for our facilities construction request, we are asking Congress to delay - for a short time - spending in this area, in order to maintain health services delivery. The one year halt in new funding for sanitation facilities projects will not interrupt IHS' plans to utilize \$237 million in previous year appropriations to bring water and sewer systems to Native American homes.

Question. Ms. Secretary, I join with Chairman Harkin in the view that medical research must be a central part of any cost savings strategy in health care reform. The discretionary appropriations process cannot keep pace with the exploding opportunities in medical research. A dedicated fund needs to be created to channel additional resources into developing new treatments for those who are sick and suffering. Senator Harkin and I have a proposal to do just that. Does the Administration have a long term strategy to address these concerns?

Answer. Our long term strategy for health care reform, including biomedical and behavioral research, is clearly laid out in the President's Health Security Act and in our FY 1995 Budget. We are committed to working with Congress to ensure that funding is available for expansion of biomedical and behavioral research, as well as the other public health initiatives

proposed. The Health Security Act includes \$1.1 billion for the "Public Health Initiative" for FY 1995, including \$400 million specifically for prevention research at NIH. We intend to work with the Congress to develop a means to ensure that the funds proposed will be made available.

In addition, our long term strategy for biomedical research includes continuing to make NIH a top budget priority, while aggressively undertaking several planning processes which will assist us in managing NIH's resources to maximize funds directly available for research. These efforts include the reevaluation of the NIH financial management plan; development of a comprehensive plan for the entire Intramural Research Program as well as a Master Plan specifically for NIH facilities; NIH's participation in the President's new National Science and Technology Council which will develop coordinated program and budget strategies for all Federal science activities; and examination over the next year by the President's Science Adviser and the OMB Director of ways to improve our policies on indirect costs of research.

Question. Ms. Secretary, the action of the House Budget Committee to reduce the recommended \$517 million increase for the NIH by \$239 million is evidence that funding for medical research is again threatened. What effect will this reduction have on your Department's ability to support medical research in FY'95. How many fewer grants would be funded? What areas of research would have to be curtailed?

Answer. The NIH funding level envisioned by the House Budget Resolution for FY 1995 would slow down our progress in all areas of basic research as well our specific investments in research areas of high need and priority. The House Budget Resolution's increase of 2.7% for NIH over FY 1994, is well below biomedical inflation of 4.1%, and amounts to a real reduction for NIH of 1.4%. The research opportunities in areas like human genetics and molecular biology are vast, and the need for research in women's health, HIV/AIDS and minority health is great. The House Budget Resolution will restrain our ability to expand spending in these areas.

Some of the directives embodied in the Resolution are of concern. While providing only 2.7% in total for NIH, the House expects a \$120 million, 40% increase for breast cancer research. While there is no greater advocate for breast cancer research and other women's health research -- we proposed a 29% increase for NIH breast cancer research -- I am concerned as to what we could do with the remainder of NIH, including AIDS research. The Resolution would also negatively effect our plans for the extramural research community, which is excited about the record number of new and competing research project grants proposed in the President's Budget. At the funding levels called for in the Resolution, the number of new and competing research project grants funded by NIH could fall as low as 6,300, or 1,000 less than the number proposed in the President's Budget.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

STATE OFFICES OF RURAL HEALTH

Question. The State Offices of Rural Health responds to growing health care provider shortages in rural America by providing matching grants for States to establish and maintain offices of rural health. I believe it is important for each State to continue building its own infrastructure to facilitate coordinated approaches to solving rural health care problems. For the past three years, the Senate Appropriations Committee has recommended that up to \$5 million be allocated to the State Offices of Rural Health grants program. Each year the Department has granted \$2.5 million for the program. The President's FY95 budget requests \$2.75 million for the program.

What is the Administration's justification for not recommending a substantial increase in the level of funding for the State Offices of Rural Health grants program?

Answer. The FY 1995 budget for the Health Resources and Services Administration proposes to extend most of its activities at the FY 1994 level. The request of \$2.8 million for the State Offices of Rural Health will continue to provide support for programs in all 50 states. We anticipate State offices to continue to play a lead role in helping rural communities develop new systems of health care and better utilize their existing resources.

Overall, the FY 1995 request includes \$548 million for rural health activities throughout the Public Health Service. The request is a \$7 million increase over FY 1994. The National Institutes of Health spending on rural health research will increase 6 percent in FY 1995 to total \$89 million. These funds will support research to address and solve the unique problems of rural health care.

Question. This seems to me to be an example of the kind of outreach program in which HHS should be involved. It has implications for increasing access to quality rural health care. Are there any obstacles to HHS' involvement in this grants program?

Answer. There are no obstacles to HHS's involvement in this grant program. We are pleased to be able to work in concert with the 50 states to help them address the problems of health care in rural communities. I would also note that the Health Care Financing Administration is supporting the new States Rural Health Network Reform Initiative program at \$7.7 million in FY 1995. This \$6 million increase will be used to help design and encourage innovations in rural health financing and delivery systems within the context of state-wide health care reform.

HEALTHY START SITES

Question. For the past two years the March of Dimes Birth Defects Foundation has funded the planning process of a Healthy Start infant mortality reduction project in the Mississippi Delta. The project has to date received no federal funds because of limited appropriations, although we were successful in securing Labor-HHS-Education Appropriations report language in FY 1993 to provide the Mississippi project with technical assistance from HHS. The report language in FY 1994 did not specify the number of sites to be funded.

The Department of Health and Human Services will soon be announcing a request for applications ("RFA") for new community-based infant mortality reduction projects, based on the model of the current funded 15 Healthy Start grants. While we do not know the exact date for the announcement, we do know that it has cleared HHS. While this is very good news it does not guarantee that the Mississippi project -- approved by HHS in FY92 but never funded due to limited appropriations -- will be a recipient of the new grants.

I understand that HHS is planning to expand funding for Healthy Start type infant mortality projects this fiscal year. I would like to work with you to help the Mississippi Delta receive funding. As you know our infant mortality rate is among the highest in nation.

At what stage are you in the process of announcing the availability of funds?

Answer. On March 23, 1994, the Health Resources and Services Administration (HRSA) announced the availability of up to \$4 million for the Healthy Start Initiative - Special Projects Grants. HRSA anticipates awarding four projects at up to \$1 million per year, renewable for a second year. These projects are expected to significantly reduce in two years high infant mortality rates in rural or urban designated project areas through acceleration of innovative strategies.

How do you anticipate this process proceeding?

Answer. The application deadline for the Healthy Start Initiative - Special Projects Grants is May 23, 1994. The applications will go through a competitive review process by expert outside reviewers. All awards will be made by September 30, 1994.

Do you anticipate receiving increased funds in FY 95 to fund these new projects adequately?

Answer. The President's Budget request of \$97.5 million in FY 1995 would fund all aspects of the Healthy Start program, including the Special Project Grants.

NATIONAL INSTITUTIONAL DEVELOPMENT AWARDS (IDeA)

Question. Last year the Committee expressed support for the Institutional Development Award program at the National Institutes of Health and directed an increase of funding of the IDeA program by National Center for Research Resources.

What is the status of this program?

Answer. The FY 1994 appropriation for the National Center for Research Resources includes \$785,000 for the Institutional Development Award program, an increase of 4.7 percent over the FY 1993 level. A new Request for Proposal has been issued, and awards will be made in September of this year.

Is the Department proposing to continue this program in the FY95 budget? If so, how.

Answer. The FY 1995 President's Budget Request includes \$900,000 to continue the IDeA program, a 14.6 percent increase over FY 1994.

Question. The Appropriations Committee, in the FY94 Veterans, HUD and Independent Agencies Appropriations bill (S. Report 102-137), directed the National Science Foundation to improve coordination and integration of all federal EPSCoR programs. In response, NSF developed a Memorandum of Understanding which five federal agencies that sponsor EPSCoR programs have signed. Those agencies (NSF, NASA, DOE, EPA, and USDA) also participate in the EPSCoR Interagency Coordinating Committee. The National Institutes of Health has not signed the MOU and does not formally participate in the Coordinating Committee.

Would you please look into this and see what needs to be done in order for the Department to participate in the EPSCoR Interagency Coordinating Committee?

Answer. Because the IDEa program is different from the EPSCoR programs of the other agencies, the Department does not formally sit on the EPSCoR Interagency Coordinating Committee. However, we have on-going formal contacts with members of the Committee from other agencies.

Would you please report back to the Committee with your findings?

Answer. Based on the nature of our interactions with other Federal agencies over the past several years and the nature of the NIH's IDEa program, NIH does not believe that formalizing our contacts with the EPSCoR Interagency

Coordinating Committee will bring about added value in administering the IDEa program.

QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

ELIMINATION OF THE ADOLESCENT FAMILY LIFE PROGRAM

Question. I noticed that you propose the elimination of the office of Adolescent Family Life and establishing in its place the Office of Adolescent Health administered by the Office of Population Affairs. You state on page 25 of Volume X of your budget justification for the Office of the Assistant Secretary for Health that OAH focuses on projects to: train health professionals; reduce the incidence of violence and substance abuse among youth; prevent adolescent pregnancy and sexually transmitted diseases; encourage comprehensive health education and the provision of contraceptive information and services to adolescents; and provide attention to the mental health needs of adolescents."

While we all applaud such a focus, I am concerned that you are suggesting we eliminate the Adolescent Family Life program which is the only federal program that promotes abstinence first as a way of preventing teen pregnancies and sexually transmitted diseases WITHOUT maintaining a similar emphasis on abstinence promotion in the Office of Adolescent Health.

Is the Administration committed to promoting abstinence? How will it do so?

Answer. Abstinence is and will continue to be an important component in the Department's various program efforts that address adolescent pregnancy. The proposed Office of Adolescent Health (OAH) will include abstinence as part of its comprehensive health education activities. The Adolescent Family Life program required teaching of abstinence, but prohibited the complementary information on contraception and avoidance of sexually transmitted diseases. For adolescents who accept the abstinence message, this is fine; but for adolescents who reject such a message and decide to become sexually active, abstinence-only messages provide no hope of protection at all against the risks of pregnancy and disease. Under the new OAH, current or new grantees who propose to conduct adolescent pregnancy prevention projects using abstinence-based curricula will be eligible to compete for funding under the new demonstration projects, but such abstinence education efforts will have to be part of more comprehensive project that includes a broader range of health, education, and social services for adolescents. I would also note that the guidelines governing the Title X national family planning program specifically stipulate that abstinence is a valid and responsible option; and our HIV/AIDS prevention efforts will continue to emphasize that abstinence is still the only way to prevent HIV/AIDS transmission.

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youth; prevent adolescent pregnancy and sexually transmitted diseases; encourage comprehensive health education and the provision of contraceptive information and services to adolescents; and provide attention to the mental health needs of adolescents."

While we all applaud such a focus, I am concerned that you are suggesting we eliminate the Adolescent Family Life program which is the only federal program that promotes abstinence first as a way of preventing teen pregnancies and sexually transmitted diseases WITHOUT maintaining a similar emphasis on abstinence promotion in the Office of Adolescent Health.

How will the Office of Adolescent Health make up for the lost focus on abstinence promotion in the Adolescent Family Life program?

Answer. Abstinence is and will continue to be an important component in the Department's various program efforts that address adolescent pregnancy. The proposed Office of Adolescent Health (OAH) will include abstinence as part of its comprehensive health education activities. The Adolescent Family Life program required teaching of abstinence, but prohibited the complementary information on contraception and avoidance of sexually transmitted diseases. For adolescents who accept the abstinence message, this is fine; but for adolescents who reject such a message and decide to become sexually active, abstinence-only messages provide no hope of protection at all against the risks of pregnancy and disease. Under the new OAH, current or new grantees who propose to conduct adolescent pregnancy prevention projects using abstinence-based curricula will be eligible to compete for funding under the new demonstration projects, but such abstinence education efforts will have to be part of more comprehensive project that includes a broader range of health, education, and social services for adolescents. I would also note that the guidelines governing the Title X national family planning program specifically stipulate that abstinence is a valid and responsible option; and our HIV/AIDS prevention efforts will continue to emphasize that abstinence is still the only way to prevent HIV/AIDS transmission.

BIOMEDICAL RESEARCH

Question. Each week I receive several letters from biomedical researchers at the University of Washington and other schools across Washington state concerned about the level of commitment by this Administration to basic biomedical research. They fear that funding increases to fight "diseases of the month" while some may be worthy, are taking away from basic science, without which, all research in the future will suffer.

How can you reassure the scientific community across the United States that basic science will be a priority for this Administration?

Answer. The 1995 budget request reflects the fact that basic biomedical research is an important investment in the future physical and economic health of the country. While the FY 1995 request for NIH includes increases for certain priority areas, well over half (60%) of the \$535 million increase for NIH is not targeted for specific disease areas. I fully understand that the results of basic research often have effects and applications in disease areas where an effect was never envisioned. For example, the basic research on retroviruses was pioneered by scientists in the National Cancer Institute. This research enables us to quickly identify the causative agent for AIDS, a prospect that could never had been imagined at the time of the initial investment. And while it is important to support the entire biomedical enterprise and infrastructure of this country, it is equally important to set priorities and provide for accelerated growth for areas of high need and promise.

QUESTIONS SUBMITTED BY SENATOR CONNIE MACK

CANCER

Question. The President's proposal emphasizes funding for breast cancer research. I'm very sensitive to this, as my wife and mother are both breast cancer survivors. Yet, if one looks at incidence, mortality and funding levels of breast cancer versus prostate cancer, or other forms of cancer affecting women, the numbers appear skewed. This is due, in large part, to Congressionally-mandated earmarks resulting from pressure from outside groups and organizations. While there were no earmarks in last year's NIH appropriations bill, the President's proposal starts Congress down the path of earmarking.

How do you view the issue of earmarking of biomedical research funding? Shouldn't these decisions be left to the research community?

Answer. I have testified on both sides of that issue. In my career as the head of a major research university I have argued strongly against earmarking. As Secretary of HHS and as a woman with long experience watching the research community, I saw women's health left out of concerns. There is now a need for some course correction.

I believe that Harold Varmus, the new Director of the National Institutes of Health, while clearly an advocate of basic, non-directed research, would also argue both sides of the question. Dr. Varmus has spent a good part of his career doing research on breast cancer, partly because of a family history of breast cancer. Yet he won the Nobel Prize for his major discovery on the brain which came out of his breast cancer research.

While some research funds are earmarked for certain disease areas, whether it's AIDS or breast cancer, much of the so-called earmarked research is actually basic science that may well give us findings in another area.

The FY 1995 NIH budget we have submitted achieves a balance between targeted research and basic science. I want you to know, however, that our fundamental commitment in the Department, as well as my personal commitment, is to supporting basic science research.

Question. Being a staunch supporter of both prevention and research activities, specifically cancer-related, I worked with this subcommittee to include language within the FY94 Senate Report to urge coordination between the Centers for Disease Control, NIH and other PHS agencies to develop a program of coordination to insure the best utilization of Federal resources for cancer control and research activities. Has this coordination been implemented and if so, how? If not, why?

Answer. We recognize the need for close coordination among Federal agencies to achieve mutual goals for cancer prevention and research. The National Cancer Institute, the Centers for Disease Control and Prevention and several other components of the Department and Federal government, have worked together to develop, and will continue to work together to implement the Breast Cancer Action Plan. In addition, the National Strategic Plan on Breast and Cervical Cancer was developed jointly by NCI, CDC and the Food and Drug Administration, along with over 150 representatives of Federal, State and local agencies and voluntary and professional groups to guide the coordination and implementation of breast and cervical cancer screening. NCI is the lead agency for the Healthy People 2000 Objectives for cancer, and coordinates activities across the Department as well as voluntary organizations such as the American Cancer Society. CDC also has major involvement in this effort and joint and complementary activities between NCI and CDC are discussed on a regular basis.

NCI also collaborates with CDC in making Surveillance, Epidemiology and End Results, also known as SEER, data tapes available to State Health Departments and other interested organizations. A State Tobacco Prevention and Control Network, staffed by the Association of State and Territorial Health Officials has been developed and is jointly funded by NCI, the Office on Smoking and Health of CDC, and the National Heart, Lung and Blood Institute. The purpose of this network is to promote the exchange of information between States on tobacco control activities and to increase coordination of these activities among State health departments.

Question. In the FY95 President's budget, the Breast and Cervical Cancer program was frozen at the FY94 level (\$78 million). Yesterday, I received a note from Dr. John Witte, Health Officer for Disease Control in the state of Florida, concerning the impact of this freeze in my state. Specifically, CDC awarded the state of Florida \$150,000 to begin planning activities to build a comprehensive early detection program. Florida has one of the highest rates of cancer in the nation, yet, I am told by Dr. Witte that the state will see no increase in funding unless the overall breast and cervical cancer program is increased. How was the decision made to freeze such a successful program, especially when the Administration has publicly emphasized the importance of cancer prevention activities?

Answer. The FY 1995 budget for the CDC breast and cervical cancer screening program sustains significant increases realized in FY 1993 and FY 1994 -- and is 56% above the FY 1992 level. Given the recent ramp-up in CDC's breast and cervical cancer program, and the difficult budget situation in FY 1995, we chose to maintain current funding levels. In addition, for the National Institutes of Health, we are requesting \$444 million for breast and cervical cancer research, an \$89 million (+25%) increase over FY 1994, and for the Food and Drug Administration, we are requesting \$20 million, an increase of \$7 million (+54%) over FY 1994, to conduct quality and safety inspections to ensure that all women have access to safe and effective mammography services. We view these as long-term investments that will improve detection, diagnosis, treatment, recovery, and eventually, the prevention of these cancers.

HEALTH REFORM

Question. Under the President's health plan, Medicare beneficiaries who take a job at a small business will be forced into the mandated health alliances paid for by employers. In essence, the plan shifts the costs from Medicare to small business owners. Even with the small subsidies, small business will be less likely to hire older workers, who naturally have higher health care costs. How do you justify this provision to shift the costs of Medicare from the government to small business owners?

Answer. The Health Security Act would not create disincentives to hire older workers.

Under the President's health plan, employees of small businesses would continue to be covered by the health alliance even after they reached 65. Employers would remain responsible for their share of premiums for all of their employees. Because the President's plan would set premiums based upon community ratings, the age of an employee as well as their health care expenditures would not alter the employer's share of premiums.

In addition, small businesses that currently offer health insurance to their Medicare eligible employees would actually benefit under this new system. They could qualify for small business subsidies specifically designed to offer financial relief for these companies, and the effect of community rating might actually lower their premium amounts.

For those small businesses that do not currently offer health care insurance, this plan would increase their financial responsibility. However, the age of their employees would not alter their responsibility because employers would be required to offer insurance (and pay premiums) for all employees regardless of age. Although there would be no additional incentive for hiring older employees and thus avoiding the cost of their health care, all employees would be treated equally and provided with the same opportunities for employer-based health insurance, regardless of age. Again, the subsidies would be provided to offer financial relief to these small businesses.

OLDER AMERICAN'S ACT

Question. Secretary Shalala, last month the entire Florida Congressional Delegation joined me in sending a letter to you regarding the Older Americans' Act. A recent GAO study concluded that the Administration on Aging is not administering the Title III funding formula according to statute, and states with large populations of older Americans are being shortchanged.

Did you receive the letter? What is your action plan to correct this inequity?

Answer. Yes, I received a letter from the Florida Congressional Delegation dated February 25, 1994. Although the Older Americans Act is very specific about the factors to consider in distributing funds to States, it is not prescriptive about the order those factors should be considered in. Our methodology, while perhaps different from GAO's is not in conflict with statutory provisions. If the Congress determines that a change is desired in the way AoA title III grants are distributed, a modification to the statute would be in order.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER BOND

COMMUNITY HEALTH CENTERS AND ACCESS TO PRIMARY CARE

Question. What are we doing to get ready for health care reform in this budget? We know we need universal coverage. But what about access to care? What are we doing to develop access points for people in underserved areas. Providing universal insurance coverage is meaningless for people that live in areas where there are not any doctors who will deliver babies or in fact, no place to get care at all. Where is the funding to fulfill this very important goal in health care reform and specifically why is there no increase proposed for community health centers which are the most cost effective way to get health care access to underserved areas? There is no increase in this budget for the national health service corps which is needed to get primary care providers into rural and underserved areas. Shouldn't we be looking to take some significant steps to solve some of these access issues as we are gearing up for comprehensive health care reform?

Answer. I could not agree with you more that insurance alone will not ensure access to care. That is why the President's Health Security Act includes a Public Health Initiative that addresses expanding access to care for underserved populations. The Public Health Initiative includes capacity

expansion and enabling services totaling \$4.5 billion from FY 1995 to FY 2000, of which \$600 million in total, \$100 million per year, is specifically designated for Community and Migrant Health Centers. The Public Health Initiative also includes a five-fold increase in the field strength of the National Health Service Corps. The plan provides \$950 million over 6 years, \$50 million in FY 1995, to achieve this goal.

IMMUNIZATIONS

Question. Your budget request for vaccine purchases includes \$424 million under the new vaccine entitlement program and an additional \$80 million for CDC immunization programs. In the solicitations for bids for the Vaccines for Children program, CDC plans to buy more vaccine than would be necessary to fully immunize every child in the United States with a great deal of vaccine left over. In one case, the solicitation is for more than three times what was estimated would be needed when Congress enacted the program.

Since the entitlement program already provides vaccines for covered by Medicaid, Native Americans and those without any health insurance, why do you need additional funds to purchase vaccines for the remaining category of families which have health insurance?

Answer. CDC is currently resurveying States to see what their needs would be outside of the new Vaccines for Children entitlement and asking them to justify that need. States have reported that they expect a large number of children who are underinsured and not eligible for the VFC benefit to seek immunization at public health clinics. In keeping with our Year 2000 goal of immunizing 90% of all 2-year olds, we believe we need to immunize every child timely no matter where they come for their shots.

Question. Your budget request also contains \$175 million for immunization outreach programs to expand access, clinic hours and education for low-income, high-risk families, and that this is \$125 million below the amount necessary for state and local health departments to implement their immunization plans.

Since most experts agree that vaccines are already available in health clinics for free and that the real problem is getting these high risk populations immunized, wouldn't it be wiser to invest scarce federal dollars in expanding immunization outreach programs rather than purchasing vaccines for families that already have insurance?

Answer. CDC believes that the \$175 million requested for State infrastructure covers the most important aspects of immunization outreach. In addition, this effort has always been viewed as a Federal partnership with States, local health departments, the private sector, and voluntary groups. We expect that these groups will contribute towards this important child health initiative. If this doesn't happen, we will reevaluate what level of funds are needed for outreach in FY 1996.

Question. Many of the health care reform proposals, including the President's, include preventive services such as immunizations in the basic benefits package that everyone will be covered with under a universal coverage plan.

What are the Administration's plans to phase-out the federal vaccine purchase entitlement as universal coverage that will cover immunizations is phased-in?

Answer. "Authorization for the vaccines for children entitlement expires upon implementation of broad-based health care reform that includes immunization service for all children." The details of how the immunization purchase entitlement would phase-out, and universal coverage phase-in, under Health Care Reform have not been finalized. This transition of vaccine programs will be one of several that will be addressed and solved as we work with Congress on the reform of our health care system.

Question. Provide a detail of administrative expenses by object class for Department agencies for fiscal years 1993, 1994, and 1995.

Answer. (Refer to the question and answer following the next one for this answer).

Question. What is the status of the HHS compliance with Executive Order 12837 which requires all agencies to submit FY 1995 budget requests that reflect no less than a 6 percent reduction in administrative expenses from the amounts made available for FY 1993? Provide an analysis of proposed Departmental reductions in the FY 1995 budget that result from this Executive Order.

Answer. While Executive Order 12837 requires that all agencies submit FY 1995 budgets to OMB that reflect no less than a 6 percent reduction in administrative expenses from amounts made available for FY 1993, budget guidance from OMB directed HHS to use a different method for estimating our administrative expenses. The OMB guidance specifically asked us to adjust administrative expenses for inflation, and then reduce the adjusted rates to an average annual increase of no more than 3 percent from FY 1995 through FY 1999. HHS complied with this guidance from OMB when preparing our FY 1995 estimates. As can be seen from the attached chart, significant reductions have been taken in administrative costs throughout HHS. Exceptions to the OMB guidance have been made in cases where significant administrative investment is critical to the function and mission of the Department. For an analysis of HHS reductions in administrative expenses, please see attached chart.

Exceptions

SSA's administrative expenses have been increased by approximately \$155 million. More than half of this increase, or \$104 million, is for SSA's automation activities. In addition, SSA will require an additional \$51 million in administrative dollars for workload-related increases for medical consultants, training and travel for processing claims and appeals, supplies, telephones, utilities, and postage for SSI claims.

HCFA's administrative expenses, like those of the Social Security Administration, are a function of both inflation and increasing workloads. If you factor in these two components, HCFA's 3.8 percent increase from FY 1993 to FY 1995 translates to a decrease of 5.5 percent based upon Office of Management and Budget assumptions.

OMB Assumptions about HCFA Administrative Expenses

Administrative Expenses		Factors	
		FY 1994	FY 1995
FY 1995	\$1,893,549,000	Inflation... 2.7%	2.9%
FY 1994	1,903,144,000	Workload.... 1.99%	1.92%
FY 1993	1,824,226,000		

Source: Office of Management and Budget

Factoring in both inflation and workload increases, the FY 1993 amount of \$1,893,549,000 is converted to a FY 1995 target of \$2,003,925,000. HCFA's budgeted spending level is 5.5 percent below this target. This level will be achieved while HCFA re-engineers its work environment to reach its FTE reduction targets, to consolidate its headquarters in a new single site, and to develop an agency-wide comprehensive strategic plan.

See Insert, ("Analysis of Change in Administrative Expenses")

ANALYSIS OF CHANGE IN ADMINISTRATIVE COSTS

(Budget Authority in Thousands)

Change from 93 to 95 Object Class	PHS:		TOTAL						AoA	OS	TOTAL L/HSE		
	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS	HCFA				SSA	ACF
Travel (21.0).....	226	(117)	3,326	(106)	(72)	230	3,487	384	11,305	151	140	(411)	15,056
Transportation of Things (22.0).....	(14)	485	896	30	1	22	1,420	161	2,294	15	27	(9)	3,908
Rental Payments to Others (23.2).....	(162)	289	2,945	7	1	0	3,080	(4,685)	186	0	2	166	(1,251)
Communications, Utilities, and													
Miscellaneous Charges (23.3).....	(106)	1,728	4,257	1,405	(2)	244	7,526	6,661	30,451	905	(13)	346	45,876
Printing and Reproduction (24.0).....	240	251	673	105	(201)	154	1,222	(549)	2,058	1,585	32	(33)	4,315
Consulting Services (25.1).....	1,985	(1,168)	(674)	(665)	0	0	(522)	16,490	3,909	45,268	3,160	(134)	68,171
Other Services (25.2).....	25,247	(25,219)	(11,171)	(11,741)	(964)	3,898	(19,950)	54,479	84,546	(33,394)	(259)	2,314	87,736
Purchases from Govt. Accts. (25.3).....	(43,087)	0	(89,976)	0	0	(7,413)	(140,476)	(2,868)	17,928	0	0	(456)	(125,872)
Operation of GOCOs (25.4).....	0	0	1,161	0	0	0	1,161	0	0	0	0	(730)	431
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	929	(507)	6,666	(321)	(3)	(10)	6,754	(750)	2,091	170	23	(64)	8,224
TOTAL CHANGE	(14,742)	(24,258)	(81,897)	(11,286)	(1,240)	(2,875)	(136,298)	69,323	154,768	14,700	3,112	989	106,594
PERCENT CHANGE	-14.70%	-22.87%	-7.38%	-9.10%	-16.07%	-14.30%	-9.29%	3.80%	25.61%	13.12%	55.25%	2.86%	2.63%

NOTES:

FY 1995 data do not reflect the FY 1995 Budget Amendments.

FY 1993 is not comparable to FY 1995.

Question. Executive Order 12837 requires all agencies to include a separate category for "administrative expenses" when submitting their appropriation requests to the Office of Management and Budget for fiscal years 1994 through 1997. Provide a detail of "administrative expenses" for Department agencies for fiscal years 1993, 1994, and 1995.

Answer. In the formal budget guidance provided by OMB for FY 1995 in the form of OMB Circular A-11, OMB did not require that Department Agencies include a separate category for "administrative expenses" when submitting their appropriation requests to the Office of Management and Budget. The administrative expenses portion of the HHS salaries and expenses exhibits has been provided in the attached table.

See Insert, ("Summary of Administrative Expenses")

SUMMARY OF ADMINISTRATIVE EXPENSES

(Budget Authority in Thousands)

FY 1995 \1 Object Class	PHS:		TOTAL		TOTAL		TOTAL		TOTAL		TOTAL	
	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS	HCFA	SSA	ACF	AOA	OS
Travel (21.0).....	3,325	11,674	21,044	1,535	372	1,037	38,987	5,478	31,971	3,651	420	3,924
Transportation of Things (22.0).....	1,218	3,556	4,113	102	49	108	9,146	431	7,120	125	72	356
Rental Payments to Others (23.2).....	0	1,469	7,790	174	9	0	9,442	0	640	0	2	182
Communications, Utilities, and Miscellaneous Charges (23.3).....	3,042	17,798	41,675	2,744	501	1,245	67,005	14,419	271,059	4,000	344	4,371
Printing and Reproduction (24.0).....	757	4,862	16,960	2,242	1,830	355	27,006	5,982	22,194	2,585	241	1,692
Consulting Services (25.1).....	12,647	649	29,103	16,835	0	0	59,234	26,618	4,100	79,846	5,173	747
Other Services (25.2).....	61,432	32,112	249,190	88,756	3,349	14,276	449,115	1,829,176	216,761	35,811	2,394	8,721
Purchases from Govt. Accts. (25.3).....	0	0	530,670	0	0	0	530,670	10,261	174,428	0	0	13,979
Operation of GOCOs (25.4).....	0	0	2,660	0	0	0	2,660	0	0	0	0	0
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	3,112	9,673	124,042	328	367	211	137,733	1,184	30,755	750	99	1,575
TOTAL, Administrative Expenses	85,533	81,793	1,027,247	112,716	6,477	17,232	1,330,998	1,893,549	759,028	126,768	8,745	35,547
TOTAL, Administrative Expenses												

1 / Data do not reflect the FY 1995 Budget Amendments.

FY 1994 Comp. to FY 1995 \2 Object Class	PHS:		TOTAL		TOTAL		TOTAL		TOTAL		TOTAL	
	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS	HCFA	SSA	ACF	AOA	OS
Travel (21.0).....	3,325	11,674	20,293	1,535	372	1,088	38,287	5,334	28,971	1,527	359	4,184
Transportation of Things (22.0).....	1,218	3,556	3,962	102	49	134	9,021	420	7,057	119	22	366
Rental Payments to Others (23.2).....	0	1,378	7,683	174	9	0	9,244	0	640	0	2	182
Communications, Utilities, and Miscellaneous Charges (23.3).....	3,042	16,432	40,669	2,744	501	1,175	64,563	11,808	242,892	3,585	295	4,264
Printing and Reproduction (24.0).....	757	4,612	16,587	2,242	2,030	373	26,601	5,829	21,251	2,462	180	1,653
Consulting Services (25.1).....	12,647	649	27,812	16,835	0	0	57,943	41,380	3,112	81,615	3,631	841
Other Services (25.2).....	55,550	35,112	228,362	88,527	3,349	14,504	425,404	1,826,692	150,257	31,833	1,974	8,404
Purchases from Govt. Accts. (25.3).....	0	0	511,130	0	0	0	511,130	10,538	164,251	0	0	13,817
Operation of GOCOs (25.4).....	0	0	2,429	0	0	0	2,429	0	0	0	0	0
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	3,112	7,673	117,835	328	367	290	129,605	1,143	28,026	489	94	1,645
TOTAL, Administrative Expenses	79,651	81,086	976,762	112,487	6,677	17,564	1,274,227	1,903,144	646,457	121,630	6,557	35,356
TOTAL, Administrative Expenses												

2 / Data do not reflect the FY 1994 salaries and expenses revision.

SUMMARY OF ADMINISTRATIVE EXPENSES

(Budget Authority in Thousands)

FY 1993 /3		PHS:		TOTAL				SSA	ACF	AoA	OS	TOTAL L/H/S/E
Object Class	HRSA	CDC	NIH	SAMHSA	AHCPR	OASH	PHS					
Travel (21.0).....	3,099	11,791	17,718	1,641	444	807	35,500	5,094	3,500	280	4,335	69,375
Transportation of Things (22.0).....	1,232	3,071	3,217	72	48	86	7,726	270	110	45	365	13,342
Rental Payments to Others (23.2).....	162	1,180	4,845	167	8	0	6,362	4,685	0	0	16	11,517
Communications, Utilities, and												
Miscellaneous Charges (23.3).....	3,148	16,070	37,418	1,339	503	1,001	59,479	7,758	3,095	357	4,025	315,322
Printing and Reproduction (24.0).....	517	4,611	16,287	2,137	2,031	201	25,784	6,531	1,000	209	1,725	55,385
Consulting Services (25.1).....	10,662	1,817	29,777	17,500	0	0	59,756	10,128	191	2,013	881	107,547
Other Services (25.2).....	36,185	57,331	260,361	100,497	4,313	10,378	469,065	1,774,697	132,215	2,653	6,407	2,454,242
Purchases from Govt. Accts. (25.3).....	43,087	0	620,646	0	0	7,413	671,146	13,129	156,500	0	14,435	855,210
Operation of GOCO's (25.4).....	0	0	1,499	0	0	0	1,499	0	0	0	730	2,229
R&D Contracts (25.5).....	0	0	0	0	0	0	0	0	0	0	0	0
Supplies and Materials (26.0).....	2,183	10,180	117,376	649	370	221	130,979	1,934	580	76	1,639	163,872
TOTAL, Administrative Expenses	100,275	106,051	1,109,144	124,002	7,717	20,107	1,467,296	1,824,226	112,068	5,633	34,558	4,048,041

3 / FY 1993 is not comparable to FY 1994 and FY 1995.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

BACK PAIN

Some of you may be aware that I recently underwent a procedure which I learned later was the subject of an evaluation by the Agency for Health Care Policy and Research's Back Pain Outcomes Assessment Team. Because my own recovery has been good, I was concerned when my own surgeon expressed misgivings about the general statistics and methodology of this very expensive survey.

Question. Our health reform system will depend on accurate and unbiased reviews of what works and what does not. How can we ensure that the studies we will rely on are done without a preordained, or intended result? How can a team funded by AHCPR be truly balanced in approach if a contract is sole-sourced?

Answer. We believe it is unfortunate that you were misinformed. AHCPR has not let a contract, sole source or otherwise, to any group nor has commissioned a panel of clinicians who are biased against surgery for back pain.

The Agency for Health Care Policy and Research did award a Patient Outcomes Research Team (PORT) grant on low back pain in FY 1989, funded through FY 1993 (P.I. Richard A. Deyo, M.D., M.P.H. -- University of Washington). The PORT is studying the relative effectiveness of different clinical interventions for low back pain. Both national and internationally known orthopedic surgeons are members of this multi-disciplinary research team and their Advisory Committee. The grant was awarded after peer review on the basis of scientific merit.

The PORT's analyses compare a variety of common diagnostic tests, alternative surgical procedures, and nonsurgical interventions. To date they have published nearly 70 articles in peer review medical journals.

One finding of the PORT has shown that patients who undergo back surgery with lumbar fusion have more complications, longer hospital stays, and higher hospital charges than patients who have back surgery without fusion. Reoperation and rehospitalization rates for back pain after four years were not lower for patients who underwent fusion procedures than for patients having surgery without fusion.

The low back pain PORT is developing educational feedback for physicians and hospitals in areas with high surgical rates. An interactive video using information from the PORT has been developed to give patients a customized presentation of the possible outcomes of surgical and nonsurgical treatment.

Further, AHCPR has facilitated development of the clinical practice guideline on acute low back problems (those that persist less than three months) through an AHCPR-approved panel of clinical experts and consumers. The contractor for supporting the guideline panel is Mikalix and Co., Waltham, Massachusetts. This contract was competitively awarded. The Low Back Problems guideline panel is chaired by an orthopaedic surgeon and the panel includes: two other orthopedic surgeons; two neurosurgeons; two internists (one a rheumatologist); two chiropractors (one is also a neurologist); two rehabilitation physicians; a health care consumer; an occupational medicine expert; a family physician; a psychologist; an occupational health nurse; a community health nurse; and a physical therapy expert.

On those topics for which contracts are awarded to facilitate the guideline process, no contracts are sole source. They are advertised through Requests for Proposals announced in the Commerce Business Daily and the National Institutes of Health Guide to

Contracts and Grants, and then competitively awarded. Current contractors for guidelines include the American Academy of Pediatrics (otitis media), RAND (heart failure) and Duke University (unstable angina).

The guideline panel will base its recommendations on management of low back problems on a thorough review and analysis of all the available pertinent scientific evidence, including findings from the PORT and expert opinion. AHCPR expects to release this guideline in the fall of 1994.

HEALTH REFORM SYSTEM

Question. Because a health reform system could require patients like me to live with back pain if the particular type of surgery was not favored by its contractors, how can we ensure that patients will indeed be able to choose a treatment methodology based on consultation with their doctors rather than with a faceless study?

Answer. The Health Security Act guarantees all Americans a comprehensive set of benefits that can never be taken away. Health plans must provide access to medically necessary or appropriate items or services specified in this comprehensive benefit package.

Decisions about what is medically necessary or appropriate are best left up to a health care provider and a patient and the Health Security Act does not get in the way of these decisions. It will not be the role of either the National Health Board or the Agency for Health Care Policy and Research to be deciding which surgeries should be paid for by health plans. The intent of outcomes research and practice guidelines is not to replace medical decision making. Only a physician and patient can together best decide what is right for that patient in that situation for that condition.

Research and guidelines serve to provide the doctor with better information with which to judge what is more appropriate and present it to the patient. Therefore the President's plan strengthens our investments in research to provide consumers and patients better information about their options while giving physicians updated information on the best available scientific evidence about "what works" in medical care.

NIOSH

I understand that Dr. Linda Rosenstock from the University of Washington has been appointed to direct the National Institute for Occupational Safety and Health, and I look forward to meeting with her.

I have with me a resolution of the Arctic Research Commission and a copy of its Chairman's letter to Dr. Lee concerning the planned closure of our small NIOSH research activity in Anchorage, Alaska. Dr. O'Dowd expresses his concern on behalf of the Commission, and encloses a copy of a letter signed by Dr. Peter Nakamura, Alaska's Director of Public Health, and Dr. Margaret Lowe, Commissioner of health and Social Services for the State of Alaska, urging reconsideration of the decision to close this important office.

I have myself received a letter from Dr. Lowe and Dr. Nakamura which identifies very difficult statistics for us in Alaska. Specifically, for the decade 1980-1989, Alaska averaged 34.8 deaths/100,000 workers/year, nearly five times the U.S. average of 7.0/100,000 workers/year. The NIOSH unit deserves particular credit for its activities resulting in a sharp reduction in deaths and injuries associated with helicopter logging in Southeast Alaska.

In 1991, the State of Alaska and the Centers for Disease Control/NIOSH entered into an agreement which specified five central objectives. I will not detail them here, but will provide them to the Committee and to your staff. Cancellation of this important activity, which has contributed to important partnerships throughout Alaska, occurred despite the fact that we have not appreciably declined in our rates of these injuries and death, although significant gains have been made in activities in the fishing and logging sectors.

The State of Alaska requests a three-year extension of this grant, particularly as it does not now possess the infrastructure nor the capacity to do these activities on its own, and would plan to take on some of these functions at the end of this three-year extension.

I will continue to pursue this issue in the FY 1995 bill, and will hope the Chairman can support my request in his initial mark.

OXYFUELS

Question. Last year, I inquired about the work of the Centers for Disease Control on the issues of oxyfuels in Alaska, and wrote in January to Dr. Ruth Etzel with a request for an update of this research.

In the past, you have indicated that while more research needed to be done on long-term effects, that there was sufficient information to suggest that the oxyfuel MTBE at least causes short-term negative health effects in Alaska, and should be avoided in the interest of public health.

What is your candid assessment of the studies done thus far on the health effects of this oxyfuel in Alaska? If additional studies are required, please describe how these studies should be designed, and what it would likely cost.

Answer. The Centers for Disease Control and Prevention (CDC) conducted a pilot study in Fairbanks during the fall of 1992 which suggested a relationship between the health complaints reported and the use of methyl tertiary butyl ether (MTBE) in oxygenated fuel. In our report "An Investigation of Exposure to Methyl Tertiary Butyl Ether in Oxygenated Fuel in Fairbanks, Alaska" dated October 22, 1993, we drew the following conclusions:

- MTBE was measurable in the blood of both workers and commuters in Fairbanks suggesting widespread exposure to MTBE during the oxygenated fuel program.

- Blood MTBE concentrations in workers were about seven times higher and more health complaints were reported during the program than after it was suspended.

- Blood MTBE concentrations increased during a workshift in direct correlation with air levels of MTBE in the workplace air.

- An association between higher blood MTBE concentrations and having a health complaint was discovered but this was not statistically significant, and a cause and effect relationship could not be proven.

- Further study was recommended to investigate the long term significance of the blood concentrations we detected.

A variety of clinical and epidemiological studies could be designed to address unanswered questions about possible health effects from MTBE use. We estimate that the cost of epidemiologic studies to further investigate the short term health effects of MTBE would be about \$2 to \$4 million dollars. Systematic risk-benefit and cost-effectiveness analyses should be considered a high priority in determining the overall health impact of the use of

MTBE in oxygenated fuel, particularly for areas such as Alaska. Such research might best be conducted by an independent organization such as the National Academy of Science. The length of time and cost required to conduct such studies would need to be worked out among the U.S. Environmental Protection Agency, CDC, and other collaborators.

BLOOD AND BLOOD PRODUCTS

Question. I have raised with Secretary Shalala and Dr. Kessler the issue of the shipment of autologous blood from small hospitals in Alaska, particularly Southeast Alaska, to hospitals in Seattle, Portland, and San Francisco so that Alaskans can utilize their own blood products when they undergo surgery.

The response so far has been disappointing. Essentially, these hospitals must go through at least three more rigorous inspections (and massive paperwork) each year to handle these relatively few cases of autologous blood transport.

They already go through rigorous testing by the Health Care Financing Administration in order to comply with CLIA regulations, they are tested to comply with JCAHO regulations, and also may be subject to other testing systems if they do not do drug testing for such industries as aviation, fishing and timber.

Can your office rely on one or more of these testing systems to preclude the expense and paperwork we would expect through FDA?

Answer. To determine if small hospitals could ship blood and blood products across state lines, the FDA Center for Biologics Evaluation and Research (CBER) conducted a review and evaluation. It was concluded that current statutory requirements demand blood banks obtain licensure authorization for shipments of autologous blood. FDA supports the use of autologous blood in all possible situations and is not in favor of a solution that includes enforcement action considerations. It is my understanding that CBER has offered to work with your staff and the small blood banks of southeastern Alaska to obtain U.S. licensure to ensure that these blood banks are in compliance with current law.

PUBLIC HEALTH SERVICE

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER BOND

HEALTH CARE FOR CHILDREN

There is more and more interest in having health care providers account for the ways in which they deliver care, the quality of the care they provide, and the outcomes of their care. The Agency for Health Care Policy and Research (AHCPR) is the center of federal work in this area. I am interested in how AHCPR addresses this issue in terms of health care for children.

Question. What percentage of the research sponsored by AHCPR in FY 1994 will be devoted specifically to issues related to health care for children?

Answer. In FY 1994 AHCPR estimates that approximately 8.5% or \$13,196,000 will be spent on projects related to health care for children.

Question. How much is AHCPR proposing to spend for children in the President's FY 1995 budget request?

Answer. At the level of the FY 1995 President's Budget, AHCPR estimates that approximately \$14,450,000 will be spent on projects related to health care for children.

Question. How does AHCPR determine each year how much of its research is devoted to issues involving health care delivery for children?

Answer. AHCPR's research agenda is influenced by a variety of factors including submission of high quality application for health services research issues relevant to children, conferences on research findings, Congressional directives and the professional judgement of AHCPR staff, input from the National Advisory Council for Health Care Policy, Research and Evaluation. Based on these factors, AHCPR may choose to direct the course of its research agenda through issuance of requests for applications (RFAs), requests for proposals (RFPs), and program announcements when new topics emerge or when the research community fails to submit high quality proposals for RO1 funding.

Program announcements and RFAs issued by AHCPR in FY 1993 and FY 1994 have resulted in research for children involving health care delivery, quality of care, and medical outcomes. In the area of health care delivery for children, recent examples of such research include a survey of adolescents' perceptions about health and health care that can be used to develop recommendations for health professionals and planners to target primary and preventive health services for adolescents; an evaluation of the effect on maternal and infant health care costs of the REACH-Futures project, an innovative service delivery model designed to reduce infant morbidity and mortality in a low income inner-city section of Chicago; two studies in a Medicaid HMO in Philadelphia that will determine the effectiveness of interventions to improve the delivery of preventive services to minority women and children; a study that will determine how clinical outcomes for children with ear infections are influenced by patient characteristics, signs and symptoms at the initial visit, day care attendance and different antibiotic strategies; and several studies that explore barriers to childhood immunization. Also of note are several studies assessing the effectiveness of public health nursing interventions in improving the delivery of recommended preventive services to children on Medicaid.

Question. Who is responsible in AHCPR for assessing the need for practice guidelines, quality and outcomes measures for children and working with the agency to establish priorities for their pediatric research?

Answer. AHCPR's Office of the Forum for Quality and Effectiveness in Health Care (Forum) arranges for the development, periodic review and updating of all clinical practice guidelines that may be used by health care practitioners and educators in determining how specific conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed. Based on the guidelines produced, the Forum oversees development of medical review criteria, standards of quality, and performance measures which assist health care providers to assess or review the provisions of health care.

AHCPR selects guideline topics and considers many factors in doing so, including:

- Potential for reducing clinically significant and unexplained variations in services and procedures used in the prevention, diagnosis, treatment, management, or outcomes related to the clinical condition.
- Number of individuals affected by the condition.
- Adequacy of scientific evidence on which to develop a guideline.
- Amenability of a particular condition to prevention.
- Specific needs of the Medicare and Medicaid populations.
- Cost of the condition to all payers, including patients.

In 1993, AHCPR released a guideline on sickle cell disease in newborns and infants and plans to release a guideline in 1994 on otitis media in children.

Research on quality and outcomes measures for children and priorities for pediatric research are considered in the larger context of AHCPR's research agenda. The factors mentioned previously, professional judgement, input from the National Advisory Council etc., would have a significant impact on establishing research priorities.

Question. Would you give the subcommittee an accounting of the research that AHCPR has sponsored related to children's health care needs since the agency was established--both the specific research sponsored and the amount of funds invested compared to the agency's total budget each year?

Answer. The information requested is provided in the following table.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
GRANTS						
Regional Variation in Pediatric Hospitalization	250,352	288,912	244,184	0	0	0
Birth Outcomes Satisfaction with Care and Malpractice	176,185	494,804	242,265	0	0	0
Childs Memory of Emergency Room	28,000	0	29,900	0	0	0
Emotional Adjustment of Children with a Chronic Illness	20,000	0	22,700	0	0	0
Nursing Interventions to Improve EPSDT Utilization	510,250	416,960	709,081	451,342	0	0
Effectiveness of Prenatal Care: Two Approaches	21,524	0	0	0	0	0
Physicians, Decisions Regarding Cerebral Palsy Referral	58,074	0	0	0	0	0
Socioeconomic Factors in Birth Outcomes: The U.S. & France	11,333	0	0	0	0	0
Full Term Intensive Care Survivors: Outcome Assessment	91,483	0	0	0	0	0
Determinants of Outcomes of Pregnancy	129,057	0	0	0	0	0
Medical policy and Infant Survivability	20,000	0	0	0	0	0
Nursing Effectiveness in Preventive Child Health Program	0	202,941	113,567	0	0	0
Cost of Neonatal Intensive Care	0	376,178	438,676	483,257	0	0
Improving Children's Health Outcomes: Negative Care	0	891,147	745,852	786,115	307,943	0
Does Health Coverage Improve Maternal Health Outcome?	0	32,500	33,800	0	0	0
Parental Leave Policies & Maternal & Infant Health	0	21,583	0	0	0	0
Components of Prenatal Care and Low Birthweight	0	125,000	0	0	0	0
Smoking Cessation in Pregnancy: A Self-Care Approach	0	25,900	0	0	0	0
Boston's Case Control Studies of Infant Death and VLBW	0	21,600	0	0	0	0
Physiologic Severity Index for Neonatal Intensive Care	0	227,090	0	0	0	0
Prophylaxis for Otitis-Prone Children	0	0	37,450	31,500	0	0

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
GRANTS						
Characterizing Families in a Pediatric Research Network	0	0	81,235	0	0	0
Management of Acute Asthma in Pediatric Practice	0	0	65,438	0	0	0
Improving the Health of Medicaid Eligible Infants	0	0	534,270	0	0	0
Child Maltreatment Reporting and Infant Mortality	0	0	21,600	0	0	0
Diffusion & Adoption of Children's Vaccine Guidelines	0	0	272,907	341,428	339,852	0
WIC Breastfeeding Promotion A Randomized Trial	0	0	21,600	0	0	0
The Effects of Rural Obstetric Care Provider Shortages	0	0	178,808	0	0	0
Primary Care for High Risk Indigent Infants	0	0	228,889	228,106	246,311	0
Infant Deaths to Teen Mothers San Antonio 1935 to 1985	0	0	20,480	0	0	0
Influence on OB Care for Minority Poor & Rural Women	0	0	76,488	0	0	0
UCLA/Medtep Center for Asians & Pacific Islanders (50%) 1/ Clinical topics include: geriatric issues, birth outcomes, hyperextension and hip fracture	0	0	195,268	195,551	200,000	375,000
Hawaii Asian Pacific Island Medtep Research Center (50%) 1/ Clinical topics include: hypertension breast cancer, tuberculosis and asthma	0	0	199,065	199,955	200,000	375,000
New Mexico Medtep Res.Ctr. in Minority Population (50%) 1/ Clinical topics include: breast & cervical cancer, type II diabetes, asthma, and substance abuse	0	0	197,637	197,174	200,000	375,000
Harlem Urban Health Research Institute (80%) 1/ Clinical topics include: Hypertension, tuberculosis, AIDS, infant mortality and teen pregnancy prevention	0	0	589,658	522,072	541,802	600,000
Morehouse Medical Treatment Effectiveness Center (50%) 1/ Clinical topics include: Hypertension, AIDS and infant mortality	0	0	186,807	199,989	200,000	375,000

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
GRANTS						
Adolescent Life Change Events, Hope and Self Care	0	0	20,000	0	0	0
Development of an Adolescent Health Status Measure	0	0	462,624	510,576	436,700	0
Strategies for Management of Dental Caries in Children	0	0	307,879	316,503	0	0
Utilization of Immunization Services Psychosocial Approach	0	0	21,600	0	0	0
MEDTEP Research Center on Minority Population, UCSF (80%) 1/ Clinical topics include: cardio – vascular disease, breast & cervical cancer, prenatal care & infant mortality	0	0	0	598,533	600,000	600,000
Research Center on Minority Health (100%) 1/ Clinical topics include: child & adolescent health and reproductive health outcomes	0	0	0	677,663	750,000	750,000
Meharry Minority MEDTEP Research Center (50%) 1/ Clinical topics include: Hypertension, substance abuse, infant mortality and chronic diseases	0	0	0	200,000	200,000	200,000
Midwest Latino Research Center on MEDTEP (50%) 1/ Clinical topics include: type II diabetes, substance abuse and infant mortality	0	0	0	174,976	218,600	200,000
MEDTEP Research Center on Minority Populations (50%) 1/ Clinical topics include: Cancer, infant mortality, low birthweight, type II diabetes and hip fracture & replacement	0	0	0	200,000	200,000	200,000
Pharmaceutical Care and Pediatric Asthma Outcomes	0	0	0	264,648	305,772	220,000
Impact of OB Practice Guidelines on Physician Behavior	0	0	0	102,180	91,562	140,000
Doctor – Patient Communication and Pediatric Prevention	0	0	0	35,300	0	0
Violence Against Pregnant Women and Pregnancy Outcomes	0	0	0	11,489	9,841	0
Poor Outcome Following Acute Otitis Media	0	0	0	1,227,372	956,596	1,199,905

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
GRANTS						
Pediatric Preventive Care Incentives in a Medicaid HMO	0	0	0	182,554	236,615	134,544
In Whose Care and Custody? Orphans of the HIV Epidemic	0	0	0	50,000	0	0
Health and Cost Impact of Maternal Child Advocate Services	0	0	0	221,048	258,038	250,000
Assessment of Febrile Infants Less Than 3 Months of Age	0	0	0	554,289	481,089	498,396
Adolescents Access to Health Care: The Teens' Perspective	0	0	0	81,250	0	0
Prospective Study of an Out-of- Hospital Birth Center	0	0	0	348,437	375,173	406,040
Factors Associated with Child Immunization	0	0	0	20,606	0	0
Risk Factors for Prenatal Drug Use and Treatment Success	0	0	0	5,005	0	0
Study of High School HIV/STD Risk Reduction Program	0	0	0	21,600	0	0
Pediatric Brain Tumor Survival: Race & Insurance Status	0	0	0	21,118	0	0
Prenatal Care Barriers After Major Medicaid Expansions	0	0	0	0	559,702	121,403
Illness Severity & Practice Variation Among Newborn ICUS	0	0	0	0	511,619	490,295
Medicaid Expansion: Impact on Pregnancy Outcome & Cost	0	0	0	0	323,721	247,672
HIV/AIDS HCSUS 1/	0	0	0	0	225,000	262,500
Estimated new awards in 1994	0	0	0	0	699,372	699,000
Estimated new awards in 1995	0	0	0	0	0	582,863
Primary care research	0	0	0	0	1,000,000	1,000,000
AIDS research	0	0	0	0	0	700,000
TOTAL GRANTS	1,316,258	3,124,615	6,299,728	9,461,636	10,675,308	11,002,618

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
CONTRACT						
HIV/AIDS ACSUS 1/	140,000	268,125	222,801	142,250	26,030	0
Pediatric Gastroenteritis	1,500,000	750,000	0	0	300,000	0
Management and Outcomes of Childbirth (PORT)	2,000,000	1,500,000	737,530	0	731,956	731,956
Low Birth Weight (PORT) (Minority & High Risk Women)	0	0	1,881,152	456,013	0	2,465,426
Development of Clinical Practice Guideline for Otitis Media in Children	0	806,099	0	207,647	0	0
Video Game to Teach Children about Tobacco	0	0	50,000	0	0	0
Maternal & Infant Health: Year 2000 IMS	0	0	42,624	0	0	0
Family Primary Care Minder	0	0	49,971	0	0	0
Family Health Reminder System	0	0	50,000	0	0	0
Family Primary Care Minder	0	0	50,000	0	0	0
A Preventive Health Care Planning Aid for Families (PREVAIL)	0	0	49,996	0	0	0
Automated Family Preventive Care Minder	0	0	55,356	0	0	0
A Family-Oriented Planning System for Primary Prevention	0	0	49,808	0	0	0
Risk-Based Screening of Families	0	0	45,900	0	0	0
A Comprehensive View of Adolescent Pregnancy and Adolescent Pregnancy Prevention in Rural Areas of the US	0	0	0	249,724	250,000	250,000
Sickle Cell Disease in Newborns and Infants (guideline)	0	0	1,000,000	0	0	0
Management of Cancer-Related Pain (guideline)	0	0	0	1,000,000	0	0
Evaluation & Management of Early HIV Infection (guideline)	0	0	0	1,000,000	300,000	0
Acute Pain Management: Operative or Medical Procedures & Tramula	0	175,000	821,385	0	0	0
CONTRACT TOTALS	3,640,000	3,499,224	5,106,523	3,055,634	1,607,986	3,447,382

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

CHILDREN'S HEALTH

PROJECT	FY 1990	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
IAAs						
Otitis Media Clinical Trail	0	0	0	89,665	0	0
Ryan White Care Act	0	0	0	10,000	0	0
Medicaid Claims Data	0	0	0	100,000	0	0
Health Care Coverage Determinations (Medicaid Claim Data)	0	0	0	0	100,000	0
Preventing Nicotine Dependence in Children and Adolescents	0	0	0	0	10,000	0
Child Development in Relation to Early Otitis Media Participating	0	0	0	0	302,706	0
Dissemination of HIV/AIDS guideline	0	0	0	0	500,000	0
IAA TOTALS	0	0	0	199,665	912,706	0
TOTAL, CHILDREN:	4,956,258	6,623,839	11,406,251	12,716,935	13,196,000	14,450,000
AHCPR's TOTAL BUDGET:	97,630,000	115,091,000	119,788,000	128,041,000	154,399,000	173,399,000

1/ A percentage of the total project award will go to Children.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Office of Emergency Preparedness

Question. I understand that HHS staff who were assigned to help with the recent horrible flooding we experienced in the Midwest spent some of the scarce Federal cash appropriated to help flood victims on themselves instead of to help the flood victims. Specifically, I am referring to reports that some people in your office purchased blue berets with this Federal money, so that they would look more like some sort of strike force. Is this report true? Does it make sense? At a time when people were suffering and needed help, what sense did it make to spend time and taxpayers dollars on frills like blue berets?

Answer. The blue berets were purchased during the Federal response to Hurricane Andrew in south Florida which, as you know, was in 1992 during the previous Administration. A total of \$3,600 was spent for this purpose, compared to over \$100 million spent by the Public Health Service on relief for hurricane victims.

The purpose of the berets was to facilitate needed identification of personnel providing medical care to storm victims. PHS commissioned corps personnel wore field uniforms similar to the military personnel operating in the area, making identification of those providing medical assistance difficult. Accordingly, blue berets bearing a PHS insignia were provided to help distinguish PHS commissioned corps personnel from the Army and Air Force personnel involved in the recovery. We believe that the cost of the berets was more than offset by the increased efficiency resulting from the better identification of medical personnel.

OASH STAFFING

Question. How many staff are working in OASH today?

Answer. The U.S. Public Health Service (PHS) is organized to fit within the Department of Health and Human Services as a principal line organization (one of five in the Department) under the direction of the Assistant Secretary for Health, who is the line manager of the eight PHS agencies. The PHS budget totals approximately \$22 billion and 51,000 employees. This budget is larger than all except four cabinet departments.

Within the PHS, the coordinating organizational mechanism is the Office of the Assistant Secretary for Health (OASH) which contains approximately one-third of one percent (about \$70 million) of the dollar resources and about 2 percent (1,177) of the staffing.

OASH is organized so that about one-fourth of the staffing is involved in supporting the Assistant Secretary in "running" the PHS which is highly decentralized. The OASH staffing as of March 19, 1994 was 1,202. The FY 1995 budget request for 1,177 FTEs supports OASH staff functions that fall into four categories as follows:

- o administrative support functions (for the health agencies and/or the Department) centralized for economy and efficiency (principally in Suburban Maryland) 493 FTEs
- o program functions in OASH as required by legislation, Executive Branch decision (this and/or previous Administrations), or to coordinate cross-cutting PHS programs (examples are Offices of Minority and Women's Health, Office of Research Integrity, Office of Emergency Preparedness) 282 FTEs
- o work done on a reimbursable basis for customers outside the Department (examples are international and refugee health programs) 125 FTEs
- o support of the Assistant Secretary in carrying out required management functions including policy development, strategic planning, budget and human resource management, grant and contract policy and procedures, equal employment opportunity, and legislative affairs and communications (this category includes health care reform activities) 277 FTEs

In response to your specific question regarding the current level of staffing in OASH, the March 19, 1994 employment totaled 1,202 employees.

Question. How many staff worked in OASH at this same time two years ago?

Answer. During the past two years the staffing level for most OASH programs and activities has been relatively stable, except for organizational changes and certain high priority areas, such as emergency preparedness, minority health, research integrity and health care reform, in which OASH has assumed additional responsibilities.

Specifically, the first of these is the establishment in OASH of the Office of Research Integrity in June 1992, for an increase of 42 employees, (this was largely a transfer of responsibilities

from the National Institutes of Health); staffing in the Office on Women's Health increased from 2 employees to a current level of 6 employees as a consequence of FY 1994 appropriations action; the Office of Minority Health staffing has increased by 20 employees to carry out the mandates contained in the Disadvantaged and Minority Health Improvement Act of 1990 (P.L. 101-527); the Office of Health Care Reform, which was established in FY 1994, had 18 employees on-board to coordinate PHS activities; and the Office of Emergency Preparedness staff has increased by 11 to respond to recurring disasters, such as Hurricanes Andrew and Iniki in 1992, the Midwest floods of 1993 and the California Earthquake in 1994, in which this office played a significant role.

The OASH staffing level two years ago totaled 1,102; however, the above organizational and program increases of 97, when added to the February 1992 on-board level of 1,102 employees result in a comparable FY 1992 staffing level of 1,199. This means the rest of OASH has decreased slightly during this period.

Question. How many of the current staff are career staff? Non-career staff? How does this compare with two years ago?

Answer. Of the current staff of 1,202, 1,081 are career employees, 14 are non-career and 107 have other appointments. The "other appointments" category includes temporary appointments of one year or less (experts); limited appointments of more than one year (Service Fellows); indefinite appointments (intermittents); and, any other type of nonpermanent appointment not otherwise covered above. In February of 1992, the career employees totaled 1,010, 11 non-career employees, and 81 other appointments.

Question. How many deputy assistant secretaries are there today, either in place or designated? How many were there two years ago?

Answer. Currently, the Assistant Secretary has a reorganization proposal pending Secretarial consideration that provides for 14 deputy assistant secretary positions. Two years ago, in FY 1992, there were 11 deputy assistant secretary positions. The additional three positions are all related to the President's health care reform proposal.

Question. What are the assignments of each of these deputy assistant secretaries?

Answer. The following is a list of the proposed deputy assistant secretary positions and a brief description of the responsibilities of each:

Principal Deputy Assistant Secretary for Health

Serves as the "chief operating officer" of the PHS; participates with the Assistant Secretary for Health (ASH) in providing advice and assistance on health and related matters to the Secretary, developing, establishing and assuring the implementation of health policy; providing leadership, direction and policy guidance to, and review and evaluation of the overall activities of the eight Public Health Service agencies; responsible for the development and maintenance of relationships with other governmental and private agencies and organizations concerned with public health matters; supervises PHS regional health administrators.

Deputy Assistant Secretary for Health

Serves as the senior advisor to the Assistant Secretary for Health (ASH) with responsibilities requiring involvement with ASH in substantive program and political matters, in policy and program development, and in the determination of, and setting of, legislative and program priorities covering the

full range of PHS activities; provides overall direction to all PHS health care reform efforts.

Deputy Assistant Secretary for Health (Policy Development)

Serves as advisor to, representative of and advocate for the Assistant Secretary for Health (ASH) providing leadership and guidance concerning selected health care reform issues. These include: expert guidance to assure policy development and recommendations on appropriate data systems needed for integrated delivery systems; policy development and recommendations on portions of the "Public Health Initiative", specifically access to health care and enabling services (Title III, Subpart E of the Health Security Act); and policy development and recommendations on school health education and school-related health services (Title III, Subpart G of the Health Security Act.)

Deputy Assistant Secretary for Health (Science)

Serves as the principal advisor to, and representative of, the Assistant Secretary for Health (ASH) on all aspects of health and scientific matters. Serves as the ASH's personal agent in coordinating Public Health Service participation in the Department's collaboration with other Federal Departments and agencies relative to health technologies; as directed by ASH, serves as Departmental liaison with the scientific community; serves as Departmental liaison with the Office of Science and Technology Policy.

Deputy Assistant Secretary for Health (Management and Budget)

Serves as the principal advisor to the Assistant Secretary for Health (ASH) for management and budget and acts for ASH in implementing and coordinating Public Health Service management activities and operational direction in areas including personnel, budget, finance, equal employment opportunity, information resources management, facilities management, and organizational analyses and recommendations.

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion and Health Planning and Evaluation)

Serves as the principal advisor to the Assistant Secretary for Health (ASH) on policies, procedures, and activities which relate to disease prevention, health promotion, preventive health services, health information and education, and evaluation; provides leadership, coordination and liaison between PHS and other Federal agencies, national non-Federal organizations, State and local agencies and private sector organizations that have roles in disease prevention and health promotion; provides leadership and coordination of PHS strategic planning efforts and represents PHS in participating in the Secretary's department-wide strategic planning efforts.

Deputy Assistant Secretary for Women's Health

Provides leadership on women's health, serving as the principal advisor and expert on women's health to the Assistant Secretary for Health and the Surgeon General. Develops overall program policies, strategies, priorities and action plans in the area. Oversees and coordinates the programs of the Office on Women's Health and the women's health programs of the agencies of the Public Health Service (PHS). Maintains liaison with key officials in the operating programs and agencies of PHS and other Government agencies to coordinate and exchange information regarding women's health activities and policies to ensure consistency with

Departmental policy. Provides professional consultation, coordination, oversight, and support to the DHHS Women's Health Program.

Deputy Assistant Secretary for Health (Communications)

Is the principal advisor to the Assistant Secretary for Health (ASH) in planning and determining communications policy and in coordinating effective and efficient performance and accomplishment of communications activities throughout the Public Health Service. These communications activities include major functions such as: public information; public liaison with appropriate associations and agencies; media relations; public appearances of the ASH; and speech writing.

Deputy Assistant Secretary for Population Affairs

Serves as the principal advisor to the Assistant Secretary for Health and the Secretary on sensitive and controversial issues regarding populations research and Family Planning Programs and Adolescent Health activities within the Public Health Service (PHS). Provides leadership in implementing the policies of PHS and the Department, within the framework of improving the health of the people and strengthening the integrity of the family. Formulates policies and recommendations which will establish goals for medical research, training and information dissemination in the fields of population, adolescent pregnancy and family planning. Applies professional public health and/or medical, clinical and research knowledge and experience in accomplishing objectives.

Deputy Assistant Secretary for Health (Interagency Relations)

Provides advice and assistance to the Assistant Secretary for Health on policy matters pertaining to health care reform activities that require coordination across major components of the Department of Health and Human Services (DHHS), especially with the Health Care Financing Administration. In addition, is responsible for liaison with other DHHS agencies on a wide variety of other policy matters that cut across agency lines and have health implications, for example, children's activities with the Administration for Children and Families and aging activities with the Administration on Aging.

Deputy Assistant Secretary for Health (Workforce and Special Initiatives)

Provides advice and assistance to the Assistant Secretary for Health on addressing the relationship between the President's health care reform proposals and issues concerning academic health centers, the health professions workforce and policies related to public health training and workforce requirements; also focuses on PHS-wide special initiatives affected by health care reform including drug abuse and mental health treatment, clinical laboratories and anti-smoking issues.

Deputy Assistant Secretary for Minority Health

On behalf of the Assistant Secretary for Health (ASH), has responsibility for Departmental activities designed to improve the health of individuals who are members of racial and ethnic minority groups and/or who are from disadvantaged backgrounds. The Deputy Assistant Secretary for Minority Health is the principal advisor who acts for the ASH in planning and determining health policies, programs and activities that address minority and disadvantaged populations. In this capacity, has responsibility for

planning, developing, establishing, coordinating, and evaluating these policies, programs and activities; works closely with the Public Health Service agencies and Departmental components in a coordinative and advocacy role; and directs the activities of the Office of Minority Health to assure achievement of minority health goals and the goals of the Administration, the Secretary and ASH.

Deputy Assistant Secretary for International and Refugee Health

The Deputy Assistant Secretary for International Health (DASIH) is responsible for overall direction of international and refugee health programs and activities in the Public Health Service (PHS). Is responsible for determining overall policies and coordination of PHS international health involvement, including representation to and participation in the programs of multilateral health organizations, bilateral programs, refugee health issues and programs and humanitarian and foreign disaster assistance. DASIH provides leadership, policy guidance and oversight for PHS' cooperation with other components of DHHS and with other Federal agencies and private sector organizations on international health matters. In accomplishing these responsibilities DASIH directs the activities of the Office of International Health and the Office of Refugee Health.

Deputy Assistant Secretary for Legislation (Health)

Responsible for coordinating and directing legislative matters affecting health activities of the Department and the Public Health Service (PHS), and for providing liaison services between PHS and the Assistant Secretary for Legislation. Provides legislative advice, policy guidance, and staff support in the area of health legislation to the Assistant Secretary for Health. Coordinates preparation of testimony or statements on legislative proposals for ASH. Maintains liaison and develops contacts with interest groups concerned with health legislation.

Question. What relationship do these deputy assistants have to PHS agency heads?

Answer. These relationships vary according to the specific program/management function being addressed. First, let me say what the relationship isn't; the deputies do not direct actions to the agency heads or their subordinates, nor do they make decisions on agency program proposals and/or budgets. The deputies are staff advisors to the Assistant Secretary for Health (ASH). The line management authority flows from the Secretary through the Assistant Secretary to the PHS agency heads and vice-versa. The ASH is the decision maker on actions not delegated to the agencies, nor reserved to the Secretary.

The relationship between the deputies and the agency heads does encompass the following: staff advice on policy and budget proposals requiring a decision by the Secretary or ASH; coordination of agency issues which involve more than one PHS agency -- issues involving AIDS, women's health, minority health, etc., very often fall into this category; advocacy of agency proposals and priorities to the Secretary's staff and other appropriate outside entities (OMB, GSA, White House staff, Congressional staff, etc.); coordination of agency interactions when it is necessary to have a single focus within PHS for its "customers" -- health care reform and Inspector General activities would be good examples of this; and soliciting of agency views, technical expertise and other input in addressing policy issues brought to the Assistant Secretary from outside PHS -- from the Secretary, the Congress, OMB, etc.

Question. Of the staff on the OASH payroll today, how many work exclusively for OASH? How many for other agencies, either full or part-time? Please list the titles of those working for other agencies.

Answer. Except for 6 employees in the Office of Health Legislation who perform dual legislative responsibilities for the Assistant Secretary for Health and the Assistant Secretary for Legislation, all staff paid by OASH funds work exclusively for OASH. However, there are staff on detail from OASH to other agencies on a reimbursable basis. These include 2 commissioned officers to the Agency for International Development; 1 commissioned officer to the Department of Energy; 1 commissioned officer and 1 civilian employee to the Department of Defense; and, 42 PHS Commissioned Officers assigned to various Immigration and Naturalization Service facilities, who provide medical and mental health care and certain other related services to detained aliens.

Question. What is the average salary of OASH staff?

Answer. The estimated average salary is \$50,756.

Question. What is the goal of OASH staff, and how does the staff arrangements listed above accomplish that goal.

Answer. As indicated in my introduction, the goals fall into four categories as follows (the supporting staff arrangements are noted parenthetically):

- Support of the Assistant Secretary in carrying out line management functions such as policy development, strategic planning, budget formulation, etc. (Principal Deputy Assistant Secretary for Health, Deputy Assistant Secretary for Health, Deputy Assistant Secretary for Health (Science), Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion and Health Planning and Evaluation) part of functions), Deputy Assistant Secretary for Health (Management and Budget) (part of functions), Deputy Assistant Secretary for Health (Communications), Deputy Assistant Secretary for Health (Interagency Relations), Deputy Assistant Secretary for Health (Policy Development), Deputy Assistant Secretary for Health (Workforce and Special Initiatives.)
- Carrying out program functions required by legislation and/or appropriations actions, such as minority health, women's health, research integrity, etc. (Deputy Assistant Secretary for Minority Health, Deputy Assistant Secretary for Women's Health, Deputy Assistant Secretary for Population Affairs, Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion and Health Planning and Evaluation) (part of functions.)
- Carrying out centralized administrative support functions on behalf of the entire PHS (or a large part of it), such as telephone and telecommunications, training, facilities management, mail management, management of the uniformed service - the PHS Commissioned Corps, etc. (Deputy Assistant Secretary for Health (Management and Budget) (part of functions.)
- Carrying out reimbursable public health efforts as requested by customers outside the Department - for example, international health and refugee health projects, (Deputy Assistant Secretary for International and Refugee Health.)

- (1) Principal Deputy Assistant Secretary for Health, Deputy Assistant Secretary for Health, Deputy Assistant Secretary for Health (Science), Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion and Health Planning and Evaluation) (part of functions), Deputy Assistant Secretary for Health (Management and Budget) (part of functions), Deputy Assistant Secretary for Health (Communications), Deputy Assistant Secretary for Health (Interagency Relations), Deputy Assistant Secretary for Health (Policy Development), Deputy Assistant Secretary for Health (Workforce and Special Initiatives).
- (2) Deputy Assistant Secretary for Minority Health, Deputy Assistant Secretary for Women's Health, Deputy Assistant Secretary for Population Affairs, Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion and Health Planning and Evaluation) (part of functions).
- (3) Deputy Assistant Secretary for Health (Management and Budget) (part of functions).
- (4) Deputy Assistant Secretary for International and Refugee Health.

CENTERS FOR DISEASE CONTROL AND PREVENTION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

VIOLENCE

Question. Dr. Satcher, I've read that, in some states, more people are killed with guns than in automobile crashes. Is this true?

Answer. Yes, in seven states (California, Louisiana, Maryland, Nevada, New York, Texas, and Virginia) and the District of Columbia, in 1991, the number of firearm-related deaths equaled or exceeded motor vehicle-related deaths. Although the number of deaths from motor vehicle crashes has traditionally exceeded those from firearms, since 1968, differences in the number of deaths has declined. From 1968 through 1991, motor vehicle crashes decreased by 21% while firearm-related deaths increased by 60%. If these trends continue, firearm-related deaths will become the leading cause of injury-related death by the year 2003.

Question. Given the fact that violence is costing this country untold misery in terms of life lost, not to mention health care costs, do you feel that CDC's budget request for the prevention of violence reflects the urgency of the problem facing this country?

Answer. Violence is clearly an urgent problem and CDC is committed to violence prevention. As we shape our priorities for CDC over the next several years, the prevention of violence is among my greatest concerns. CDC's approach, which applies traditional public health principles used in the eradication of smallpox and in the reduction of infectious disease, is an important part of a meaningful strategy to prevent violence. I believe that we must develop the capacity within our communities to respond to these problems, and we must forge new partnerships and

nurture old ones. We have a responsibility to work with the churches, schools, businesses and organizations in our communities as well as with various federal, state and local agencies that have a compelling interest in preventing the number one threat to our nation's youth. CDC's budget request includes funds for working with communities to prevent violence at the same time we are developing the science base to better understand the causes of violence.

TOBACCO USE

Question. Smoking costs the nation \$72 billion per year in health and lost productivity. It is the single largest preventable source of death and illness. Do you think that your budget is adequate to meet the need for a national effort to reduce the use of tobacco?

Answer. CDC is very proud of the significant advances that have been made with the increases in tobacco funding during FY 1993 and FY 1994:

- In FY 1994, CDC provided funding to 32 States and the District of Columbia--currently 14 States receive funds for planning/capacity building activities, and 19 States receive funds to fully implement activities for tobacco prevention and control programs. All States (except California) are now receiving some level of federal funding for tobacco prevention and control programs either through CDC or through the National Cancer Institute's ASSIST program (17 States).
- Up to 10 cooperative agreements will be awarded to national organizations during FY 1994 to help build internal capacity for tobacco control issues among their constituents and to become leaders in the tobacco prevention and control movement.
- Follow-up activities to this year's Surgeon General's report are being conducted, including "Youth & Elders," a nationwide teleconference to encourage local communities to employ the conclusions from the Report, and the Surgeon General's first report for kids about smoking--the SGR4Kids magazine.
- CDC is evaluating the effect of the Synar Amendment on tobacco-purchasing behaviors and the initiation of tobacco use.

In FY 1995, with existing funds, CDC plans to increase funding to several States to assist them in implementing their tobacco control plans and will explore new opportunities to distribute State-produced counter-advertising materials nationwide.

While CDC's accomplishments are significant, there is still much to be done. CDC will take advantage of every possible opportunity to enhance our efforts in prevention and tobacco control activities.

Question. Last year's report language urged the use of counter-advertising to reduce the incidence of tobacco use among children and teenagers. What have you done in this regard?

Answer. With new resources provided by Congress, CDC is making advances in both research and application. An entire chapter of this year's Surgeon General's Report was devoted to the effects of advertising on young people; this information will be of great assistance to States, CDC, and others in developing program and policy interventions. Additionally, current studies underway indicate the link of cigarette advertising expenditures with teenage brand preference. CDC will analyze the Teenage Attitudes and Practices Survey (TAPS) II data on youth prevalence, brand preference, and access to cigarettes, and will present the results.

CDC conducted the "Youth & Elders Against Tobacco Use" national teleconference and produced 3 million copies of the Surgeon General's first report for kids about smoking, SGR4Kids, which has a strong counter-advertising component. A planned public information campaign focusing on secondhand-smoke in the workplace will include TV, print, and radio advertising, and CDC's toll-free information hotline for requesting copies of a free action guide. The California Department of Health Services has agreed to CDC distributing nationally their tobacco control media materials. These materials will be distributed through agreements with State health departments and supplemented with training materials and other assistance. CDC is collaborating with the Center for Substance Abuse and Prevention to update and expand the "Performance Edge" campaign, which highlights the negative physical and social effects of alcohol and tobacco use, and to produce a media campaign to de-glamorize the use of alcohol and tobacco use among teenagers.

CDC takes pride in its accomplishments this year in counter-advertising, while contending with a \$4 billion tobacco industry expenditure on advertising and promotion.

FTE CUTS

Question. What impact are the cuts in FTE having on CDC's ability to make staff assignments to the states in lieu of grant monies?

Answer. The required shrinking workforce at CDC will seriously impact the use of FTEs in lieu of grant monies. The reduction in FTEs is currently planned to be attained through attrition. Under this approach, CDC is estimating that if attrition was essentially equal across CDC, the number of FTEs assigned to States in lieu of grant monies would be reduced in FY 1995 by 53 (6 percent reduction) compared to FY 1994 and by 106 (11 percent reduction) when compared to FY 1993.

Question. What impact are the cuts in FTE having on CDC's ability to conduct applied research?

Answer. Activities in support of applied research will be unavoidably impacted by the cuts in FTEs. The actual impact will be determined by where attrition takes place.

EPIDEMIC INTELLIGENCE SERVICE

Question. Dr. Satcher, I've always been very impressed with CDC's Epidemic Intelligence Service--also known as the disease detectives. This committee has provided increased resources so that more individuals could receive training. What is the current status of this program?

Answer. Consistent with its 43-year history, CDC will be bringing in a new Epidemic Intelligence Service (EIS) class this July. This new class consists of 66 Officers, and includes the 20 additional positions CDC received in FY 1991. However, in keeping with the President's plan to reduce FTEs, a change has been made in the administration of the EIS Program. Thus, the 1994 EIS Class will receive fellowship awards rather than being hired on a limited-tour basis through the PHS Commissioned Corps or the CDC Visiting Program. This change is considered to better characterize the Officers status as trainees. Despite this administrative change, programmatic requirements remain the same. The change to a fellowship will enable Officers to complete the same learning activities as in the past, including serving at the forefront of disease investigation, prevention, and control. CDC's ability to provide rapid response to emergent public health problems is greatly facilitated by this cadre of uniquely trained public health practitioners; and, therefore, the excellence in our EIS training will be maintained.

CHILDHOOD IMMUNIZATION INITIATIVE

Question. Dr. Satcher, CDC has the responsibility of implementing the President's Childhood Immunization Initiative. What are the key elements of this program?

Answer. The President's Childhood Immunization Initiative (CII) has established goals of reducing most diseases preventable by childhood vaccination to zero, increase vaccination levels for 2-year-old children to at least 90 percent for the initial and most critical doses in the vaccine series, and 70 percent for a more recent vaccine (Hepatitis B), and build a vaccine delivery system to maintain these achievements in the United States within a reformed health care system. The CII will concentrate on the following five key elements to achieve these goals.

- 1) Improving the quality and quantity of vaccination delivery services. Activities related to this element include: providing funding for implementation of the Immunization Action Plans developed by 87 State, Territorial, and local health agencies to enhance the vaccine delivery infrastructure; advocating the use of the *Standards for Pediatric Immunization Practices* by all vaccine providers to remove barriers to immunization and eliminate missed immunization opportunities; strengthening involvement of private health care providers in achieving the CII goals; and, assisting States in developing Statewide Immunization Information Systems to remind parents when vaccinations are due for their children.
- 2) Reducing vaccine costs for parents. The Omnibus Budget Reconciliation Act of 1993 authorized the establishment of the Vaccines for Children (VFC) program which will provide free vaccine to about 60 percent of our Nation's children. Eligible children include those who are Medicaid eligible, those without any health insurance, and American Indians. The VFC is intended to remove cost as a barrier to immunization.
- 3) Increasing community participation, education, and partnerships. This component seeks to increase awareness of the importance of age-appropriate immunization and increase community participation and efforts to educate and mobilize parents and providers.
- 4) Improving monitoring of disease and vaccination coverage. Funding and scientific/intervention assistance is being provided to public health agencies to improve surveillance and investigation of vaccine-preventable diseases. Comprehensive systems are in place or are being developed to monitor immunization coverage to provide local, State, and National data to help target interventions to improve immunization levels.
- 5) Improving vaccines and vaccine use. Efforts are underway to develop a single childhood immunization schedule to reduce confusion about when the 11-15 separate immunizations that are required prior to the second birthday should be given. The Public Health Service (NIH, FDA, and CDC) will work with the manufacturers and researchers to stimulate development of new and combined vaccines to reduce the number of immunizations. CDC will also work on enhancing systems to detect rare adverse events following vaccination, which will lead to the provision of better information to parents on the risks and benefits of vaccination.

Question. What will be the impact of this program on the ability of state and local health departments to provide vaccines to children whose health insurance coverage does not include immunization services?

Answer. The Vaccines for Children (VFC) legislation requires children whose health insurance does not cover immunization to seek free immunizations under the VFC program at Federally-Qualified Health Centers (FQHCs). The FY95 budget request includes \$80 million for immunization grantees to purchase vaccines for those children they currently serve who are not covered by the VFC program. In addition to these Federal funds, the States can continue to use the funds they have traditionally committed to purchasing vaccines to serve the underinsured children who are unable to seek immunization at FQHCs. We believe that the total amount of funds available for the purchase of vaccine will be sufficient to purchase vaccine for all underinsured children.

AGRICULTURAL SAFETY AND HEALTH

Question. Dr. Satcher, one of the first things I did upon becoming Chairman of this Subcommittee was to add funding for an Agriculture Safety and Health program within NIOSH. I continue to be concerned over studies that have shown elevated mortality rates for different types of cancer among farmers. Therefore, I am very pleased that CDC has established working relationships with universities, state health departments, and others in almost half of the states. Can you tell me how this program is working?

Answer. The NIOSH Agricultural Safety and Health Program is funding 51 programs in 25 States: the Farm Family Health Hazard Survey, Occupational Health Nurses in Agricultural Communities, Centers for Agricultural Occupational Safety and Health, Cancer Control for Farmers, and Agricultural Health Promotion Systems are now in their fourth year of funding. Coordination of all of these efforts occurs through a variety of media, one of which will be a CD-ROM system that will include agricultural health and safety information from participants nationwide. This database, to be on-line later this year, will allow all NIOSH program grantees access to all documents created as part of the agricultural safety and health program. In addition to the programs listed below, NIOSH is continuing studies in agriculture-related lung diseases, noise-induced hearing loss, musculoskeletal disorders, stress, and pesticide illness. The following describes examples of program accomplishments during the previous fiscal year.

Centers for Occupational Safety and Health in Agriculture: NIOSH is funding six centers in Kentucky, New York, California, Iowa, Colorado, and Wisconsin. Accomplishments this year include completion of research on farm-related fatalities of California children, in which machinery was found to be the most frequent cause of farm-related trauma ending in death, completion of a survey on pesticide illnesses, development of techniques for reducing musculoskeletal injuries in a dry bean processing plant, and a workshop on farm flood response for local government agencies, relief organizations, and businesses.

Agricultural Health Promotion Systems: NIOSH is funding systems in 18 states: Arizona, California, Colorado, Florida, Iowa, Kansas, Michigan, Missouri, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Vermont, Virginia, Washington, and Wisconsin. Examples of accomplishments this year include development of model safety programs and tractor rollover safety demonstrations for high schools and community colleges, and presentation of ten Farm Women's Safety Workshops.

Farm Family Health and Hazard Survey: Surveys will be conducted in six states: Colorado, Ohio, Iowa, California, Kentucky, and New York. Three states, (Colorado, Ohio, and Iowa) are currently "in the field" collecting health and hazard data by survey and on-site farm visits. The three remaining states are in the process of finalizing their respective survey proposals.

Occupational Health Nurses in Agricultural Communities (OHNAC): The program presently has placed 30 nurses in 9 states: California,

Iowa, Kentucky, Maine, Minnesota, New York, North Carolina, North Dakota, and Ohio. The nurses have identified a wide range of hazards which have been described in MMWR articles, local newspapers, and other journals. These include pesticide poisonings, power take-off-related injuries, occupational respiratory diseases, tetanus, day care needs, spouse abuse, depression, Green Tobacco Sickness, carbon monoxide poisonings, grain suffocations, and ergonomic hazards associated with blueberry harvesting. This program has also initiated a survey to describe work experiences of school-aged children in blueberry harvesting.

Cancer Control Project for Farmers: Control programs are funded in 12 states: California, Delaware, Iowa, Georgia, Maryland, Michigan, Minnesota, Nebraska, North Carolina, Wisconsin, Virginia, and West Virginia. Work underway includes analysis of the incidence and mortality of cancer due to breast and colon cancers, melanoma, and non-Hodgkin's lymphoma in farming populations, and programs for detecting and preventing melanoma, breast, and cervical cancer among migrant farm workers.

Question. Are there any areas of missed opportunities?

Answer. Yes, there are always missed opportunities. The cost of the opportunities have to be evaluated against other competing health needs and reducing the National debt. We are very pleased that this request includes a \$5,000,000 increase for occupational safety and health.

EARTHQUAKE IN CALIFORNIA

Question. What has been CDC's role in responding to the earthquake in California?

Answer. CDC has been providing assistance to minimize the health problems which can result from an earthquake. The CDC maintains a 24 hour emergency system to respond to disasters. The CDC Emergency Operations Center was opened within one hour of the earthquake and began coordinating activities with PHS Region IX and the Office of the Assistant Secretary for Health. CDC emergency response staff were deployed to the area to begin coordinating the CDC response from the health department and from the Federal Disaster Field Office. In the early phase of the response, CDC epidemiologists assisted the county epidemiologists in developing and implementing a scientifically based rapid needs assessment in the most affected area. This rapid assessment was used to help guide the health response to the community. Throughout the response, CDC staff provided on-site and telephonic technical assistance to state and local health officials in the areas of public health surveillance, injury control, health education, disease control, and environmental health. On January 23, 1994, CDC Director, Dr. David Satcher, made site visits along with county health department officials to one of the encampment/tent cities and to one of the county health clinics where a Disaster Medical Assistance Team was working.

At the request of the state and Ventura County, a CDC team is currently investigating a possible earthquake related outbreak of valley fever (coccidioidomycosis).

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

OCCUPATIONAL SAFETY AND HEALTH LABORATORY

Question. The new occupational safety and health laboratory is expected to be completed and ready for occupancy in 1995. This facility will house the new Division of Laboratory Health Effects Research, which will require an additional 310 FTE, 41 of which have been hired.

When do you expect to have the director and branch chiefs on board for the new laboratory?

Answer. The plans for the new laboratory call for the recruitment of the new director and branch chiefs in FY 1994, but we have not allocated additional FTEs in FY 1994, nor are additional FTEs proposed in the FY 1995 budget.

Question. How many staff do you expect to hire in FY 1994 and FY 1995?

Answer. The plans for the new laboratory call for recruitment of 111 additional people in FY 1994 and 158 in FY 1995, but we have not allocated additional FTEs in FY 1994, nor are additional FTEs proposed in the FY 1995 budget.

Question. Please furnish the timetable for completion and occupancy of the new laboratory.

Answer. The new laboratory is on schedule to be completed and ready for occupancy by mid-1995.

FTE LEVELS - APPALACHIAN LABORATORY

Question. Please provide the FTE levels for the Division of Safety Research and the Division of Respiratory Disease Studies at the Appalachian Laboratory for Occupational Safety and Health in FY 1992, FY 1993, FY 1994 and on the projected levels for FY 1995.

Answer. Following are the FTE levels for the Division of Safety Research and the Division of Respiratory Disease Studies for FY 1992, FY 1993, FY 1994 and the proposed level for FY 1995.

Division of Safety Research

	FY 1992	104.4 FTE
	FY 1993	108.4 FTE
	FY 1994	108.4 FTE
Projected	FY 1995	108.4 FTE

Division of Respiratory Disease Studies

	FY 1992	151.8 FTE
	FY 1993	155.8 FTE
	FY 1994	155.8 FTE
Projected	FY 1995	155.8 FTE

FUNDING LEVELS - APPALACHIAN LABORATORY

Question. Please provide the funding level for each of the above Divisions for FY 1992, FY 1993, FY 1994 and the projected levels for FY 1995.

Answer. Following are the funding levels for the Division of Safety Research and the Division of Respiratory Disease Studies for FY 1992, FY 1993, FY 1994 and the projected levels of funding for FY 1995.

Division of Safety Research

	FY 1992	\$9,258,000
	FY 1993	\$11,019,000
	FY 1994	\$14,130,000
Projected	FY 1995	\$15,130,000

Division of Respiratory Disease Studies

	FY 1992	\$13,530,000
	FY 1993	\$15,040,000
	FY 1994	\$15,238,000
Projected	FY 1995	\$15,238,000

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

YOUTH VIOLENCE

Question. Dr. Satcher, I am particularly concerned about what has been called the epidemic of violence among our youth. I have been holding hearings in my subcommittee of the Judiciary Committee on the problems of young people who join gangs, which often engage in violence. I understand that the Public Health Service, particularly in CDC, has begun looking at youth violence as public health threat.

Could you describe your findings to me, and any suggestions you have come up with about what we can do to stem the tide of violence which seems to be stealing the future from so many of our young people?

Answer. Violence is a complex problem, with many causes -- and there are no simple solutions. Our approach, therefore, must use a number of different activities that are selected based on the unique characteristics of a particular community. These prevention activities are combined to create a program that is likely to work in a given community. At this time, there are no certain solutions. However, there are violence prevention activities which show tremendous potential to alleviate the trauma of violence. CDC is currently funding activities to help communities and is supporting evaluation research to determine what works to prevent violence.

For example, CDC supports three youth violence demonstration projects to identify successful methods for delivering youth violence interventions at the community level, and to determine if multifaceted community programs can reduce the rates of violent behavior, injury and death associated with youth violence. CDC has also recently funded the evaluation of 13 intervention projects to determine what works to prevent violence. These interventions include conflict resolution, social skills training and peer mentoring. In addition, CDC has published a guide to help communities design and conduct their own violence prevention programs. The guide, "The Prevention of Youth Violence: A Framework for Community Action," includes examples of promising interventions that are underway in many communities across the nation.

TB EPIDEMIC - DISTRICT OF COLUMBIA

Question. Dr. Lee, I understand that the Public Health Service, through the CDC, recently documented the extent of the TB epidemic currently sweeping through the District of Columbia. As I understand it from the press reports on this study, the jail and prison populations have particularly high TB rates, and I am concerned about how well TB is being controlled in these environments, since these people often bring diseases they pick up while incarcerated back into the community, hastening the spread of this epidemic. I also understand that one big problem is that the city lacks access to a laboratory capable of determining whether or not someone has multi-drug resistant TB. I have several questions about this situation.

Could you please summarize the findings of the recent CDC study?

Answer. The Centers for Disease Control and Prevention (CDC) did not conduct the review of the District of Columbia tuberculosis program. The Commissioner of Public Health for the District of Columbia requested the review which was conducted by the American Lung Association of the District of Columbia (ALADC) of the District's tuberculosis prevention and control activities. The ALADC assembled a group of experts to serve on a Special

Tuberculosis Assessment Committee, of which the membership included some CDC staff. The Committee's final report contains detailed conclusions as well as a summary of findings and recommendations and has been provided to the Commissioner of Health.

Question. What next steps does the CDC report recommend?

Answer. A Special Tuberculosis Assessment Committee, convened by the American Lung Association of the District of Columbia (ALADC), conducted the review of tuberculosis prevention and control activities in the District of Columbia. CDC did not conduct the review although some CDC staff served on the ALADC review committee at the request of the Commissioner of Public Health for the District of Columbia. The Committee's report ranks recommendations in order of priority.

Question. Is CDC implementing those recommendations?

Answer. The recommendations were developed by the Special Tuberculosis Assessment Committee for the District of Columbia Tuberculosis Control program. This Committee was convened by the American Lung Association of the District of Columbia (ALADC). One of the Committee recommendations related directly to CDC. The Committee recommended that the District of Columbia Department of Health seek an immediate outside technical review of the health department's mycobacteriology laboratory and that the review should be conducted either by CDC or a CDC recommended consultant. Subsequently, at the request of the District Public Health Laboratory Director, a CDC team conducted an evaluation of the laboratory program on March 16 and 17, 1994. A written report of this assessment is being prepared and will be presented to the Commissioner of Public Health and Director of Laboratories for the District.

In general support of national TB prevention and control activities, CDC is providing Tuberculosis Cooperative Agreement support to the District of Columbia Health Department for FY 1994 in the amount of \$662,519, a substantial increase over the \$361,047 funded in FY 1993. CDC will also continue providing guidance, support and technical assistance needed to help implement the recommendations.

Question. If the District lacks access to sophisticated lab services necessary to help stem this epidemic, could not some of the many PHS labs in this area, including those operated by NIH and FDA, be made available to help out until the District can get such a lab up and running?

Answer. Operationally, the Commissioner of Health for the District of Columbia would need to contact NIH and FDA to facilitate availability of their laboratory resources. In November 1991, to address interdisciplinary and interagency issues regarding national TB prevention and control efforts, CDC created the federal TB task force which comprises representatives of agencies of the Public Health Service (including NIH and FDA), the Health Care Financing Administration, the Department of Housing and Urban Development, the Occupational Safety and Health Administration, the Department of Veterans Affairs, and the Federal Bureau of Prisons. Through the task force, many implementation steps leading to TB elimination will be collaboratively suggested and undertaken.

Question. Is this TB epidemic enough of a crisis that we need to take such bold action, or do you think business as usual will suffice?

Answer. The Special Tuberculosis Assessment Committee convened by the American Lung Association of the District of Columbia found that tuberculosis is still an important problem for the District of Columbia with the potential for significant increases in cases and possible outbreaks. For these reasons, the Committee made recommendations for expanded efforts and actions to improve the situation.

QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

E. COLI 0157:H7

Question. As you are no doubt aware, in January 1993, four children died and more than 600 people became ill from undercooked meat at Jack in the Box restaurants in four western states. The outbreak was caused by a deadly bacteria known as *E. coli* 0157:H7 which lives in the intestines of cows and can contaminate meat during slaughter.

Extensive research on *E. coli* 0157:H7 has been conducted by Dr. Phil Tarr and others at Children's Hospital and Medical Center in Seattle, Washington which is where many of the children affected by the *E. coli* outbreak were treated. Dr. Tarr is currently researching ways to prevent *E. coli* from entering the food supply in the first place.

In the Senate report accompanying the HHS appropriations bill for fiscal year 1994, the CDC was directed "to commit additional resources to *E. coli* research field work in Washington state." Has any funding been used for this purpose to date?

Answer. CDC continues to make significant resource commitments to the *E. coli* 0157:H7 outbreak that occurred in Washington State. In 1994, CDC has worked closely with the Washington State Health Department in conducting ongoing epidemiologic and laboratory activities to determine the persistence in the community of the *E. coli* strain that caused the January 1993 outbreak, and to determine sources of additional clusters of *E. coli* infections. Specific epidemiologic and laboratory based activities have included determining the relationship of human and food isolates of *E. coli* 0157:H7, and comparing strains responsible for current illnesses to the one that caused the large outbreak in 1993.

Since the large outbreak in January 1993, CDC has tested isolates for types of toxins produced and has subtyped isolates from 5 different outbreaks of *E. coli* 0157 infections in Washington. CDC continues to investigate *E. coli* strains by modern molecular biologic techniques to determine how long the January 1993 outbreak strain persisted in the community.

In February 1994, CDC assisted with the investigation of *E. coli* illnesses occurring in Washington and Oregon which were unrelated to the January 1993 outbreak. These illnesses initially appeared to be sporadic, unrelated cases from unknown sources; however, laboratory and epidemiologic evidence have now shown that the illnesses came from the same ground beef source which was bought at a variety of local grocery stores, thus determining that the cases in the two states are related. CDC has had important roles in coordinating the federal interactions with the state health department. Two persons from USDA have been assigned to work at CDC and to participate in the ongoing investigation of this outbreak in collaboration with CDC and the Washington and Oregon State Health Departments.

Washington state continues to have sporadic illness, as well as clusters, caused by *E. coli* 0157:H7. CDC will continue to provide assistance to the state health department in the investigation of these cases.

Question. What future work is planned with regard to *E. coli* 0157:H7?

Answer. To combat ever-growing foodborne hazards, a comprehensive, integrated, intramural and extramural program, including enhanced surveillance for acute and chronic adverse health effects of infectious pathogens, such as *E. coli* 0157:H7 in

food; epidemiologic and laboratory investigations; and prevention and control strategies for foodborne pathogens are critically needed.

CDC is designing a comprehensive program of foodborne disease prevention and control to be carried out in collaboration with state and local health departments, FDA, USDA, academic communities, and the food industry. The program will provide financial and technical assistance to state and local health departments to reinforce surveillance and investigation activities of foodborne disease. Improved state and local public health laboratory capacity to detect and monitor emerging foodborne pathogens are critical components of a foodborne disease prevention program. Strengthened prevention and control strategies, including educational campaigns to increase awareness of the public of methods of reducing foodborne disease risks; community-based demonstration projects; and special epidemiologic investigations will be essential components of the program.

Specific activities of the program would include:

- assistance to state health departments to ensure the capacity to monitor for, detect, investigate, and control foodborne pathogens as infections occur;
- establish regional intervention units in specific state and local areas, in existing public health laboratories, to collaborate with CDC in developing and conducting targeted epidemiologic and laboratory investigations;
- enhance state public health laboratories in laboratory investigations of foodborne pathogens through targeted training and transfer of molecular methods of diagnostic testing to these laboratories;
- assure rapid communication of surveillance, epidemiologic, and laboratory data on foodborne disease through communication "superhighways;"
- develop health communication strategies and educational messages for high-risk consumers;
- incorporate educational components on the prevention of foodborne disease into school health education curricula;
- develop and communicate risk of and preventive measures for foodborne disease to health care providers; and
- identify problems requiring further applied research, and provide justification for regulatory change.

Question. Have you coordinated any of your *E. coli* research with Washington State University and Dr. Phil Tarr at Children's Hospital?

Answer. We are in frequent contact with Dr. Dale Hancock of Washington State University and with Dr. Phil Tarr of Children's Hospital. The CDC investigations of *E. coli* O157:H7 complement those of these research investigators. CDC has assisted Dr. Hancock by analyzing isolates obtained from cattle that were linked to persons who became ill after drinking raw milk. CDC compared the *E. coli* O157:H7 isolates from cattle to those isolated from ill persons. We have also collaborated with Dr. Tarr to determine the prevalence and clinical significance of variations in the toxin genes of human *E. coli* O157 isolates.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER BOND

BIRTH DEFECTS SURVEILLANCE SYSTEM

Question. We know that more than half of the states have no system to monitor the incidence and study the causes of birth defects. How much would they need to set up an effective nationwide, state-based birth defects surveillance system?

Answer. The ideal nationwide, state-based birth defect surveillance system would include every state. As you mentioned, only half of the states have any kind of surveillance system. These states are currently spending about \$7 million on these systems, but many of those systems are not able to provide reliable data in a timely fashion, as would be required for a national surveillance system. Therefore, many of these states would need financial assistance to upgrade their systems and the other half of the states would require financial assistance to begin new systems. We believe that about \$25 million would be required to begin a national birth defect surveillance system, most of this money going to states to help them collect and analyze data. This level of funding would be sufficient for each state to collect basic surveillance data to monitor incidence or for several states to have high quality systems which would help find new causes of birth defects as well as monitor incidence. The states would pass on this data to CDC to incorporate into a national data system. The states would also use the data to set prevention priorities, monitor prevention efforts, and estimate services needed for children and adults with disabilities associated with birth defects. Some of the money would be used to develop computer software to make it easier to use computerized hospital discharge data for surveillance.

Question. Over the past few years, this subcommittee has provided funding for birth defects prevention. How do you plan to spend the 94 funding for birth defects prevention activities and what are CDC's plans for FY 95?

Answer. In FY 1994, CDC received \$7.5 million for prevention and surveillance of birth defects. This money is being used to support the following projects:

1. Two birth defects risk factor studies (California, Iowa) to find new causes of birth defects.
2. Two neural tube defects surveillance and prevention programs (South Carolina, Texas).
3. Five state fetal alcohol syndrome prevention programs (Oklahoma, Washington, Georgia, Montana, Colorado).
4. Three university research and development programs for fetal alcohol syndrome (University of New Mexico, University of Washington, University of Cincinnati).
5. Study of effectiveness of 0.4 mg of folic acid in community prevention program in China.

CDC plans for FY 1995 are to continue the above projects at the same level of funding.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

SPRANS Reduction

Question. The President's budget proposes reducing the Maternal and Child Health Block (MCH) Grant by \$8 million in fiscal year 1995 from \$687 million to \$679 million. Appropriation language has been proposed to take this reduction in the SPRANS (Special Projects of Regional and National Significance) program while maintaining the level of payments to States and for CISS (Community Integrated Service Systems). Funding for SPRANS would be reduced from \$101 million to \$93 million.

What is the rationale for this reduction?

Answer. The Block Grant is being reduced by \$8 million because of overall constraints on discretionary spending imposed by the Budget Enforcement Act.

Question. Why is the reduction proposed to be taken only from SPRANS?

Answer. The reduction is being targeted to SPRANS so that funds for services to mothers and children will be maintained at the FY 1994 level. It is important to note that maternal and child health research programs, at the National Institute of Child Health and Human Development, propose a significant increase.

Question. What type of projects will not be funded due to the proposed reduction in funding?

Answer. The SPRANS reduction of \$8 million will be taken from research and maternal and child health improvement projects. This will result in an estimated reduction of 6 research grants totalling \$1.2 million and 45 Maternal and Child Health Improvement Projects (MCHIP) totalling \$6.8 million. The reduction will eliminate funds to support new research and demonstration projects addressing such MCH issues as infant mortality, adolescent health, injury prevention, minority health, immunizations, children with special health care needs, youth services and technical assistance to States for data collection and analysis. On going projects will not be affected.

Question. How are SPRANS activities reflecting this Committee's concern for rural and smaller urban areas?

Answer. In response to Congressional intent, the MCHB will place special emphasis on improving the continuing problem of high infant mortality in regions of the United States whose rates are unyielding to current approaches or resources. Recent reports of high infant mortality in rural areas and smaller urban communities have indicated the need for initiatives in these areas. Therefore, MCHIP projects under the Infant Mortality Reduction priority are expected to target populations living in rural areas and smaller urban communities whose total population is less than 250,000 at the most recent national census and which have a documented three year average Infant Mortality Rate that exceeds the 1991 national average of 8.9 infant deaths per 1,000 live births.

The specific MCHIP Infant Mortality Reduction project categories are:

1. "Development of Perinatal Care Systems" category which seeks to reduce infant mortality in rural areas and smaller urban communities through project support for development and expansion of community-level perinatal care systems. These systems are public-private community partnerships of health-related and other relevant organizations and individuals working collaboratively. These partnerships utilize a variety of resources to address community-identified perinatal health problems; and
2. "Family Support and Preventive Services Following Infant Deaths" category whose purposes are to support families following an infant death by expanding or initiating comprehensive and integrated information and counseling systems of services; and, to reduce infant mortality by providing updated preventive information concerning the reduction of risks for infant mortality. Funds are available to support projects whose service boundaries encompass smaller urban and/or rural areas.

Community Integrated Service System

Question. Please describe CISS Projects.

Answer. The CISS program seeks to reduce infant mortality and improve the health of mothers and children, including those living in rural areas and those having special health needs, through project support for development and expansion of community integrated services systems. These systems are public/private partnerships of health-related and other relevant community organizations and individuals working collaboratively to use community resources to address community-identified health problems.

The CISS program requires that at least one of the following program strategies be utilized: (a) Maternal and infant home visiting; (b) activities that increase the participation of obstetricians and pediatricians in publicly funded MCH services; (c) one-stop shopping; (d) MCH centers operated under not-for-profit hospitals; (e) increased access to MCH services in rural areas; and (f) outpatient and community-based service programs for children with special health needs.

In FY 1993, 9 new CISS grants were awarded for a 4-year project period from the total of 175 new applications submitted to MCHB. In addition, 32 CISS grants funded in FY 1992 received funds for their second year of operation.

The Administration for Children and Families (ACF) and the Health Resources and Services Administration (HRSA) have agreed to collaborate to assist States in developing comprehensive systems of care which meet both the health and welfare needs of families. In FY 1994 this collaboration will be manifested by a supplementary discretionary grant program which will complement state planning activities under the Family Preservation and Support Act. The program specifically will support efforts which focus on integrated community

systems of care, include at risk pregnant women as well as children and their families as the target population, pay particular attention to the increased resources needed by children with special health needs and their families, emphasize primary prevention and family support activities, and use a system of home visiting as a significant component of any community system of care. Through this program ACF and HRSA hope to amplify the impact of the Family Prevention and Support Act and, consistent with the wish of Congress', to move toward carrying out the intent of the "Home Visiting for At Risk Families" title of the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act (P.L. 102-321). The application for this complementary grant program, one per state, may be submitted by any entity but must be developed collaboratively with representatives of the State agency administering the Title IV-B Child Welfare programs and the Title V Maternal and Child Health Program.

Family Planning Services

Question. The Administration has proposed a \$199 million or 10 percent, increase for family planning services and that increase will support the expansion of service sites and provide services to an additional 300,000 clients.

Has there been any plans made to target this increase primarily to services for adolescents, in particular, outreach activities?

Answer. Title X Family Planning Clinics are the primary point of contact for many adolescents into the health care system. The rising sexual activity rates among adolescents and concerns about prevention of sexually transmitted diseases (STDs) have increased the need to expand family planning services, particularly for low income women and adolescents. The FY 1995 request of \$198.9 million is an increase of 10 percent over the FY 1994 appropriation. The proposed increase will provide funds to support the following activities:

- o outreach to low-income women, adolescents, and high risk or unintended pregnancy or infection with STD not now receiving family planning services;
- o increased focus on quality and completeness of services including treatment of STDs, screening for cervical cancer and prevention of breast cancer, substance abuse counseling, and counseling on avoidance of high risk behavior which may place clients at risk of STD and HIV;
- o more emphasis on prevention of adolescent pregnancy through enhanced counseling;
- o expansion of current clinics sites and development of clinics in high need areas to provide services to an additional 300,000 clients; and
- o more emphasis on training and retention of Family Planning nurse practitioners, particularly minority practitioners and those working in clinics serving high need populations.

Two of these priorities specifically target adolescents; while the other three address systemic needs of the program which will help

improved services to adolescents, who currently comprise about one-third of the clientele of the Title X program.

Consolidation of Health Profession Programs

Question. The Administration has proposed the consolidation of over 25 categorical health profession programs into five consolidated grant programs.

The proposed consolidation would eliminate a number of categorical health professions programs, including programs for physician assistants, programs in public health and preventive medicine and programs for the allied health professions. Do you plan to maintain fiscal year 1994 funding levels for these programs within the consolidation?

Answer. The FY 1995 request of \$267 million for Health Professions programs is a net decrease of \$15 million or five percent below the FY 1994 appropriation. It is now envisioned that consolidation of Health Professions and Nursing programs can be achieved over a two year period, working with the Congressional authorizing committees to give grantees more flexibility in directing resources. The FY 1995 categorical amounts are:

Minority/Disadvantaged Health Professions Initiatives:

Centers of Excellence.....	\$23,481
Health Careers Opportunity Program.....	24,961
Loan Repayment/Fellowships - Faculty.....	<u>1,053</u>
Subtotal.....	49,495

Consolidated Student Assistance Program:

Exceptional Financial Need Scholarships...	10,433
Financial Assistance for Disadvantaged	
Health Professions Students.....	6,241
Loans for Disadvantaged Students.....	7,925
Scholarships for Disadvantaged Students...	<u>17,102</u>
Subtotal.....	41,701

Primary Care/Public Health Education Initiatives:

Allied Health Special Projects.....	2,300
Area Health Education Centers.....	21,050
Chiropractic Demonstration Grants.....	0
Family Medicine - Training & Departments..	44,742
General Dentistry Training.....	1,600
General Internal Medicine & Pediatrics....	15,972
Geriatric - Training & Education Centers..	6,652
Health Administration Traineeships &	
Special Projects.....	994
Health Education & Training Centers.....	2,832
Pacific Basin Medical Officer's Training..	1,422
Physician Assistant Training.....	6,213
Podiatric Medicine - Primary Care Training	0
Public Health & Preventive Medicine.....	7,410
Rural Health Interdisciplinary Training...	<u>3,600</u>
Subtotal.....	114,787

Priority Nursing Education Initiatives:

Increasing Nursing Workforce Diversity....	3,693
Nurse Practitioner, Nurse Midwife, & Other Advanced Practice Nursing.....	44,931
Strengthening Capacity for Basic Nurse Education and Practice.....	<u>9,860</u>
Subtotal.....	58,484

Health Professions Research & Data:

Health Professions Data System.....	1,642
Research on Certain Hlth Profession Issues	<u>1,122</u>
Subtotal.....	2,764

Total Titles VII & VIII.....\$267,231

Question. Do you believe that the unintended effect of federal spending policies, particularly under Medicare, is an excess supply of practitioners in specialties and a shortage of supply in primary care?

Answer. Yes. Specifically, the unintended effects of Medicare graduate medical education (GME) payment policies include:

- (1) **Encouraging training in hospital settings and discouraging training in non-hospital settings.** This is because Medicare payments for direct medical education are currently paid to hospitals rather than training programs or educational institutions.
 - o Medicare GME payments go only to hospitals. Medicare will make direct GME payments for training in non-hospital settings, but only to hospitals which bear costs for that training. This appears to give the hospital control over reimbursement for GME training sites and is a disincentive to incorporating independent ambulatory sites which can be key to primary care GME programs. No IME is paid if training is in non-hospital setting. Although more primary care training should take place in non-hospital ambulatory settings, hospitals have a great incentive not to train residents in such settings.
- (2) There is an imbalance between direct and Indirect Medical Education (IME) Medicare payment policies, in that direct costs are paid at the full (1.0) rate only for the years of training necessary for the initial certification, but indirect costs are paid for all years of residency training regardless of length or extent of specialization or subspecialization. Because the indirect payment is on average over twice as much as direct, this imbalance greatly weakens the disincentive that Congress apparently intended when it eliminated an extra year of residency training from full Medicare direct reimbursement.
- (3) **Providing incentives to recruit residents simply to meet individual and institutional hospital service and budgetary needs, rather than according to any national physician workforce plan for a desired number and specialty mix.** This is because:

- o Medicare pays GME without regard to numbers or specialty mix of residents in a hospital.
 - o The IME ("indirect") adjustment is paid at a higher rate than is justified by analysis of GME-related hospital operating costs, which subsidizes hospital services, thereby giving hospitals an incentive to keep or add residents to gain the subsidy.
 - o On average, hospitals receive \$70,000 per resident from Medicare alone in direct medical education and IME payments. Residents generate this added Medicare payment, whereas alternative practitioners (staff physicians, nurse practitioners or physician assistants) must be paid for out of regular (non-GME) Medicare hospital payments.
 - o Residents provide considerable assistance to faculty in caring for their patients and assisting in their research, particularly since faculty tend to be highly specialized in major teaching centers.
 - o Hospitals have service demands, particularly in inner cities, which can be advantageously met through having residents and being reimbursed for them, without direct relevance to the Nation's physician workforce needs.
 - o All GME funds go into general hospital revenues and are not attributable to GME purposes.
- (4) Fundamentally, there is no national physician workforce plan guiding the allocation and limitation of GME funds. Because of the many competing incentives described above, we are producing too many specialists and too few generalists given the Nation's health care needs.

Funding of Migrant Health Centers

Question. In both the Senate and House Committee reports, the Migrant Health Center programs were directed to use the additional funding received in fiscal year 1994 to support the increased costs of providing services in existing health centers.

Has the Bureau addressed this need in fiscal year 1994?

Answer. The FY 1994 increase of \$1,694,000 for MHCs will be made available to existing MHCs to support the increased cost of providing services to their current patients. Funds will be used to support current service adjustments in MHCs. Current service adjustments, where applicable, allow the centers to show the need for additional funds to maintain the existing range of services to the current number of users when existing levels of service cannot be funded with the total Federal and non-Federal revenue reasonably estimated to be available. Included is support for the recruitment and retention of health care providers in MHCs, service education linkages with academic institutions, school-based or school-linked programs, and activities to address high prevalence morbidity and mortality (e.g., HIV/AIDS).

These funds will also be used to support MHC improvement proposals that enhance the provision of basic required services. The improvement proposals for which funding may be made available include the following required services: dental, pharmacy, culturally sensitive/translation services, and case management.

Question. With proposed level funding in fiscal year 1995, will migrant health centers be able to maintain existing level of services?

Answer. Due to expanded grant funding in FY 1991 to FY 1994, changes in Medicaid eligibility and increases in Medicaid revenues, the C/MHC program has been able to provide access for over 1 million additional migrant and seasonal farmworkers and their families since FY 1991. Based on this previous experience, we anticipate that some additional increase in Medicaid revenue will continue to occur. In addition, with the anticipated savings realized from discounted pharmaceutical prices, vaccine purchase and immunization infrastructure funding from CDC to the States earmarked for C/MHCs, we believe that MHCs will be able to maintain their current service levels and serve at least the same number of patients.

Federal Torts Claims Act Coverage for CHCS

Question. In 1992, Congress extended Federal Torts Claims Act coverage to Community Health Centers and their employees to help reduce the grantees' insurance costs.

Have all community Health Centers now been deemed eligible for federal coverage?

Answer. To date, 475 out of 600 Community/Migrant Health Centers have been deemed eligible for Federal coverage. The remaining grantees are in the process of review.

Question. What savings have resulted from the extension to FTCA coverage to Community Health Centers?

Answer. We do not yet have information about the savings that have resulted from FTCA coverage. Although insurance companies have given health centers estimates of the costs of the "tail" and "gap" insurance which would be necessary to supplement FTCA coverage, health centers are having difficulty getting insurance companies to actually issue such policies. Based on estimates by insurance companies of the costs of various forms of malpractice insurance coverage, no more than 30 percent of the centers might experience cost savings with FTCA coverage.

Immunizations at Community Health Centers

Question. How many children receive immunizations at Community Health Centers?

Answer. Approximately 500,000 children age 0 - 2 receive immunizations at Community Health Centers.

National Health Service Corps Defaults

Question. Of the National Health Service Corps scholarships awarded since 1988, what percentage are in default?

Answer. Of the 1,274 scholarships awarded for the six fiscal years 1988 through 1993, 27 or 2.1 percent of the awardees have been declared to be in default status to date.

Question. What actions are being taken to collect the delinquent amounts?

Answer. The NHSC aggressively pursues post-default efforts to obtain service, collect debts, and protect the Government's interests.

The debt collection protocol is:

- Three 'due diligence' letters are sent.
- Efforts are made to have the defaulter enter a 'Repayment Agreement' to retire the debt.
- Delinquent debts are referred to a private collection agency.
- Delinquent debts are referred to a credit reporting agency.
- Delinquent debts are referred to the Internal Revenue Service to offset Federal income tax refunds.
- Efforts are made to obtain a voluntary agreement to have Medicare reimbursements offset by the Health Care Financing Administration.
- Efforts are made to establish salary offset agreements with individuals who are Federal employees and have delinquent debts.
- Delinquent accounts are referred to the Department of Justice (DOJ) for enforced collection.
- The U.S. Marshall's Service is authorized to attach assets.

Efforts made to obtain service in lieu of monetary repayment:

- Until the case is referred to the DOJ, service is offered under the terms of a 'Forbearance Agreement'.
- After the case is referred to the DOJ, service may be offered under terms of a consent judgement.
- After a judgement is obtained by the DOJ, execution of the judgement is stayed if the individual agrees to serve.

Current efforts to protect the Government's interests:

- Distribute the names of defaulters who are serving, paying or neither to PHS agencies for the purpose of monitoring service or for potential employment information.
- Distribute the names of delinquent defaulters to other agencies in the Department involved in advisory committee appointments or hiring consultants.

Proposed efforts to protect the Government's interests:

- An amendment to the Privacy Act Systems of Records Notice to allow circulation of names of delinquent defaulters to other Federal departments.
- A legislative change to authorize listing the names of delinquent defaulters in the Federal Register.

FTE Reductions

Question. Your request funding level for program management incorporates a FTE decrease of 69 FTE as a result of reinvention efforts and program consolidation.

Will the reduced staffing levels impact your ability to adequately monitor your grantees?

Answer. Over the past 5 years, HRSA has introduced new management activities to perform necessary programmatic functions. These include Total Quality Management (TQM), establishment of Quality Councils, installation of local area computer networks throughout the Agency, and establishment of Quality Improvement Teams which are reviewing the grants award process. These improvements were necessary as discretionary budget caps were enforced which restricted Program Management. The FTE level included in the President's budget provides the FTE level necessary to adequately monitor programs.

Question. If the Health Services Programs consolidation is not approved, will you still be able to take the decrease of 25 FTE to be achieved as a result of that consolidation?

Answer. If the proposed consolidation of Health Professions programs is not approved, HRSA will take steps to achieve the 25 FTE reduction throughout the Agency.

Monitoring Ryan White Funding

Question. The Public Health Service plays a major role in funding programs for the prevention and treatment of AIDS. It has distributed over \$500 million in Ryan White funds to eligible metropolitan areas.

How does the PHS monitor the use of these funds by its grantees and subgrantees to ensure that such monies are well spent?

Answer. The PHS monitors the use of funds by its Title I grantees and subgrantees in a variety of ways, including quarterly and end of year financial status reports. Each eligible metropolitan area (EMA) is also required to submit quarterly reports focusing on their progress in meeting stated goals of delivering priority services to populations of clients in need. Additionally, there are periodic project officer and grants management reviews of expenditures and grantee administrative oversight of subcontractor spending.

HRSA requires that grantees submit information in their applications for supplemental funds on the proposed program uses of both their formula and supplemental awards. These uses must be based on a standard population specific needs assessment process (with technical assistance provided by the HRSA) and the priorities determined by the EMAs' planning council.

Question. What actions has PHS taken as a result?

Answer. What actions we take depend, in part, on what we've found and the circumstances involved. Last year, in response to the Committee's question for the record about types of problems (other

than funding) cities have encountered in making emergency assistance services available to AIDS patients under Title I of the Ryan White CARE Act, we noted that "among the problems encountered have been availability of resources, service delivery infrastructure, difficulties in awarding contracts rapidly, managing conflicts of interest in planning councils, and issues of selecting the most appropriate providers for each community." Since that time we have been able, through technical assistance efforts, to work closely with the grantees to improve the rapid disbursement and administrative oversight of contractor spending of funds, strengthen capacity building efforts to develop infrastructure in underserved minority communities, and better manage conflict of interest through the development of appropriate by-laws and procedures.

Question. How does the PHS report on its monitoring activities?

Answer. HRSA carries out its monitoring of grantee disbursement of funds and contract oversight as required by Department and PHS policies, procedures and guidelines. Reviews of the appropriateness of priorities and plans for spending funds and procedures to administer funds are carried out annually as part of the Title I supplemental competitive grant review process.

Question. Has PHS monitoring of grantees and subgrantees affected subsequent funding decisions? Describe actions PHS has taken in response to improper expenditures or other problems disclosed by external auditors.

Answer. With respect to Title I, subsequent funding decisions are limited by certain statutory and non-discretionary requirements. One half the available funds each fiscal year must be distributed automatically according to a formula and the remaining half is distributed on a competitive basis based on documentation of additional critical needs by the eligible areas. As part of the competitive application process for supplemental Title I awards we have taken several steps to ensure timely and appropriate uses of grant funds. These include establishment of criteria in the applications for supplemental funds which requires that grantees report on the following:

1. Their progress in implementing their current year's plans. This includes the implementation of program objectives and success in rapidly allocating Ryan White funds to contractors (subgrantees) providing services.
2. The EMA's plans for the use of the currently requested funds; and
3. A description of the EMA's system for the program and fiscal performance monitoring of its contract service providers. Under this criteria, EMAs must describe their systems for securing programmatic and fiscal reports from contractors, the frequency of the required reporting, and the indicators for, and planned types of corrective actions.

These three criteria total 69 out of the possible 100 points that may be assigned to an application being rated for supplemental funding. In making a final determination, those EMAs whose

application receive higher overall scores receive more money relative to their formula awards than those EMAs with lower overall scores. To date no external audits of improper expenditures or uses of funds have been needed.

With respect to our response to improper expenditures by Title I grantees, such reports by EMA contractors are closely reviewed by HRSA staff for the appropriateness of the expenditure, and referred to the EMA (the grantee) for investigation and resolution, if required.

Question. Please provide copies of all PHS reports associated with this subject.

Answer. There are no specific reports on PHS monitoring activities. In addition to grantee applications, related reports include quarterly financial and program status reports from each grantee and project officer site visit reports. If the committee finds it desirable, HRSA would provide summaries of the end of year financial status reports for Fiscal Year 1991 and Fiscal Year 1992. Data for Fiscal Year 1993 is not yet available.

Increased Funding for Ryan White Programs

Question. Your budget request includes an increase of \$93 million for Ryan White programs.

How did you determine the distribution of the increase among the Ryan White programs?

Answer. The increase of \$39 million for Title I is intended to provide funds to assure that eligible metropolitan areas (EMAs) funded in FY 1994 do not receive less in FY 1995 than they received in 1994. This amount takes note of newly eligible areas.

The increase of \$30 million for Title II will provide additional funding to meet the needs of an increased number of clients who live longer and require new and more expensive pharmaceuticals. In addition they permit States to expand home health, insurance, and consortia programs. The increase is also intended to assure that this Title is funded at approximately the same percentage of total Ryan White funding in FY 1995 as it was in FY 1994.

The increase of \$19 million for Title III reflects the additional funding needs for early intervention and treatment at Community Health and Migrant Health Centers and other outpatient primary care centers located in areas to which the HIV epidemic has spread recently. This program has been funded at essentially the same level for the past four years. It will enable the delivery of services to an estimated additional 38,000 people through an additional 54 health care sites.

The increase of \$5 million for Title IV will assist in developing comprehensive HIV care for women and children in community settings which have recently been impacted by the HIV epidemic. The funds will also assist communities and facilities respond appropriately to the recent clinical trial results which show that AZT given during pregnancy and delivery can prevent some of the transmission of HIV to infants.

Ryan White Title II Funds

Question. How are the States using their Ryan White Title II funds?

Answer. Ryan White Title II funds have been awarded to 54 States and Territories and are used to support four types of programs to provide services to people infected with HIV. All programs are not implemented by every state.

The four programs and preliminary estimates of the percentage of funds used based on information states submitted with their applications for FY 1993 grants are:

HIV care consortia to plan, develop, and deliver a comprehensive continuum of out-patient health/support services. Twenty (20) states are legislatively required to do this, by virtue of having reported at least 1 percent of the AIDS cases nationwide during the previous year. States meeting this criterion spent an average of 59 percent of their funds for this purpose. An additional 22 states also have care consortia and allocate an average of 50 percent of their funds for this purpose. Based on preliminary reports for FY 1993, approximately 53 percent of the FY 1993 total amount awarded to the States was spent for this activity.

Home and community based care. Twenty-two states elected to fund this activity. They reported spending an average of nearly 19 percent of their funds for home care. In FY 1993 approximately 4 percent of the total amount awarded was spent for this program.

Continuity of health insurance. Nineteen states reported spending an average of 12 percent of their funds on this activity. In FY 1993 approximately 3 percent of the total amount awarded was spent for this program.

Treatment (AIDS drug reimbursement). Forty-seven states report spending an average of more than 39 percent of their funds for this purpose. In FY 1993 approximately 33 percent of the total amount awarded was spent for this program.

States may use up to 5 percent of their funds for administrative purposes and not more than 5 percent of their funds for planning and evaluation.

Title II funds may not be used to provide services covered under the State Medicaid Plan, to make direct payments to service recipients or to replace/supplant state HIV/AIDS funding/in-kind resources.

The following table reflects the aggregate of Title II Ryan White Funds in Fiscal Years 1991 and 1992 and projected allocations for FY 1993. The amounts shown for FY 1993 are based upon preliminary reports submitted by grantees in FY 1993, and are subject to change upon receipt of final reports.

Ryan White Title I Supplemental Awards

Question. When do you expect to award Ryan White Title I supplemental awards?

Answer. Ryan White Title I Supplemental awards were made March 21, 1994. Listed below are both the formula and supplemental awards to the 34 metropolitan areas eligible for FY 1994 Ryan White Title I funds.

<u>EMA</u>	<u>Formula Grant</u>	<u>Supplemental Grant</u>	<u>Total Grant</u>
Atlanta, GA	\$4,066,062	\$3,422,739	\$7,488,801
Baltimore, MD	2,232,355	1,691,083	3,923,438
Bergen-Passaic, NJ*	1,277,031	742,090	2,019,121
Boston, MA	3,091,876	3,863,159	6,955,035
Chicago, IL	4,706,676	4,918,775	9,625,451
Dallas, TX	3,445,177	3,490,467	6,935,644
Denver, CO*	1,626,755	1,749,129	3,375,884
Detroit, MI	1,623,489	1,226,070	2,849,559
Fort Lauderdale, FL	3,555,421	3,259,178	6,814,599
Houston, TX	5,676,753	4,456,839	10,133,592
Jersey City, NJ	2,306,302	1,833,839	4,140,141
Kansas City, MO*	1,251,712	1,403,852	2,655,564
Los Angeles, CA	12,617,337	12,823,874	25,441,211
Miami, FL	6,875,102	8,383,461	15,258,563
Nassau-Suffolk, NY	1,403,882	1,483,086	2,886,968
New Haven, CN*	1,235,428	901,444	2,136,872
New Orleans, LA	1,691,877	1,551,455	3,243,332
New York, NY	45,835,380	54,218,887	100,054,267
Newark, NJ	5,166,261	1,842,919	7,009,180
Oakland, CA	2,379,546	1,549,741	3,929,287
Orange County, CA	1,426,850	1,201,097	2,627,947
Orlando, FL*	1,319,944	1,395,643	2,715,587
Philadelphia, PA	3,479,453	3,895,483	7,374,936
Phoenix, AZ*	1,175,959	1,041,512	2,217,471
Ponce, PR	976,793	200,000	1,176,793
Riverside-			
San Bernadino, CA*	1,299,021	1,102,989	2,402,010
Saint Louis, MO*	1,178,039	1,070,208	2,248,247
San Diego, CA	2,696,880	2,536,694	5,233,574
San Francisc, CA	19,056,960	20,153,440	39,210,400
San Juan, PR	4,561,223	3,894,834	8,456,057
Seattle, WA	1,617,949	1,615,954	3,233,903
Tampa-			
St. Petersburg, FL	1,955,256	1,349,056	3,304,512
Washington, D.C.	5,225,866	4,102,846	9,328,712
West Palm Beach, FL*	1,959,886	1,622,656	3,582,542
TOTAL	\$159,994,501	\$159,994,499	\$319,989,000

*NEW EMA IN FY 1994

Eligible Metropolitan Areas

Question. According to your budget submission, the FY 1995 budget request for Title I must support the funding of three to seven new metropolitan areas.

What are the seven metropolitan areas that may be eligible for Title I funding in FY 1995?

Answer. We are currently estimating that 3-7 metropolitan areas may be eligible for Title I funds in Fiscal Year 1995. Final eligibility will be determined based on cases reported to the CDC as of March 31, 1994. Two cities -- Jacksonville, Florida and Caguas, Puerto Rico -- have qualified as of September 1993.

It is conceivable (depending on January-March reporting) that several more metropolitan areas could become eligible by March 31, 1994, including Minneapolis, MN and San Antonio, TX.

Question. What are the 34 metropolitan areas currently eligible for Title I funding?

Answer: The following is a list of the current 34 EMAs:

Atlanta, GA	New Haven, CT
Baltimore, MD	Newark, NJ
Bergen-Passaic, NJ	Oakland, CA
Boston, MA	Orange County, CA
Chicago, IL	Orlando, FL
Dallas, TX	Philadelphia, PA
Denver, CO	Phoenix, AZ
Detroit, MI	Ponce, PR
Fort Lauderdale, FL	Riverside-San Berardino, CA
Houston, TX	San Juan, PR
Jersey City, NJ	San Francisco, CA
Kansas City, MO	San Diego, CA
Los Angeles, CA	Seattle, WA
Miami, FL	St. Louis, MO
Nassau-Suffolk, NY	Tampa-St. Petersburg, FL
New York, NY	Washington, DC
New Orleans, LA	West Palm Beach, FL

THE ALLOCATION OF TITLE II RYAN WHITE CARE ACT FUNDS IN FY 1991 AND 1992 AND PROJECTED ALLOCATIONS FOR FY 1993

PROGRAM PURPOSE	ALLOCATION OF TITLE II FUNDS BY FISCAL YEAR		
	FY 1991	FY 1992	FY 1993*
HIV CARE CONSORTIA	\$38.8 million (50%) (40 grantees)	\$49.1 million (51.6%) (42 grantees)	\$54.0 million (52.8%) (42 grantees)
HOME & COMMUNITY BASED CARE	\$2.3 million (3%) (25 grantees)	\$4.1 million (4.3%) (24 grantees)	\$3.7 million (3.6%) (22 grantees)
HIV/AIDS TREATMENT (AIDS Drug Reimbursement)	\$28.3 million (36.5%) (50 grantees)	\$31.7 million (33.3%) (48 grantees)	\$33.2 million (32.4%) (47 grantees)

*NOTE: Amounts shown for FY 1993 are based upon preliminary reports submitted by grantees in FY 1993, and are subject to change upon receipt of final reports.

THE ALLOCATION OF TITLE II RYAN WHITE CARE ACT FUNDS IN FY 1991 AND 1992 AND PROJECTED ALLOCATIONS FOR FY 1993

-CONTINUED

PROGRAM PURPOSE	ALLOCATION OF TITLE II FUNDS BY FISCAL YEAR		
	FY 1991	FY 1992	FY 1993*
INSURANCE CONTINUATION	\$1.3 million (1.7%) (16 grantees)	\$2.3 million (2.4%) (16 grantees)	\$3.2 million (3.1%) (19 grantees)
ADMINISTRATION, PLANNING & EVALUATION	\$6.8 million (8.8%)	\$8.0 million (8.4%)	\$8.3 million (8.1%)
TOTAL FUNDING	\$77.5 million	\$95.2 million	\$102.4 million

Guaranteed Loan Programs

Question. The Public Health Service maintains a guaranteed student loan program for individuals entering the health care profession. The Department of Education has recently moved to eliminate its guaranteed loan programs in favor of direct loans, which are far less costly to the government.

Has the PHS evaluated its guaranteed loan programs to determine if direct loans would be more efficient? If so, what was the result?

Answer. The PHS has evaluated the Health Education Assistance Loan (HEAL) program, its guaranteed loan program for health professions students, to determine if direct loans would be more efficient. As a result of this evaluation, it has been determined that the following differences between the Department of Education (ED) guaranteed loan programs and the HEAL program support maintaining HEAL as a guaranteed loan administered by HHS rather than converting it to a direct loan program administered by ED:

- (1) Unlike most of the ED guaranteed loan programs, the PHS pays no direct interest subsidies on HEAL loans. Instead, the total cost of the HEAL loan is paid by the HEAL borrower. This includes interest on the loan, which accrues from the date the loan is made and is added to the borrower's total debt, but is not payable by the borrower until the repayment period begins. Thus, while the federally subsidized interest makes the ED guaranteed loans extremely costly to the government, there is no comparable cost incurred by the government for HEAL loans.

- (2) While there is no direct Federal subsidy to be saved by converting HEAL to a direct loan program, such a change would require an additional Federal appropriation of at least \$375 million per year for the foreseeable future in order to continue HEAL lending activity at its current level. On the other hand, maintaining HEAL as a guaranteed loan allows us to leverage the same amount of funds--\$375 million per year--at a Federal cost of only \$28 million, the amount that the government must contribute to the HEAL insurance account to maintain its solvency.
- (3) While the HEAL statute authorizes lenders to charge interest at a rate as high as the quarterly T-bill plus 3 percent, interest rates on HEAL loans are currently as low as the quarterly T-bill plus 2.1 percent. The reduced rates are the result of a competitive bidding process, under which lenders must compete annually for HEAL insurance authority. The reduced HEAL interest rates have saved borrowers a total of \$370 million since the competitive bidding process was adopted in 1991, and have resulted in HEAL interest rates which currently are lower than the interest rate charged on ED's unsubsidized loan program. Given that the interest rates on ED's unsubsidized loans are higher, it is doubtful that the significant cost savings that have been achieved for borrowers under the HEAL program's competitive bidding process could be maintained if HEAL were converted to a direct lending program.
- (4) The HEAL program is unique among Federal loan programs in its focus on health professions students. Given the health care reform activities underway in the Congress and the Administration, it seems prudent to maintain HEAL as an HHS program so that it can be used as a source of leverage to shape the health care work force in a manner that is supportive of health care reform. For example, legislative amendments could be enacted which would limit eligibility for HEAL to those health disciplines for which there is a demonstrated national need.

While the above factors strongly support maintaining HEAL as a guaranteed loan program, there are several caveats which should be noted:

- (1) Maintaining HEAL as a guaranteed loan program is somewhat inconsistent with the movement toward simplification and consolidation of Federal student loan programs, since it may continue to necessitate separate loan application and tracking procedures for students who have both direct loans from ED and HEAL loans.
- (2) It is our sense that HEAL lenders will continue to be interested in making HEAL loans, regardless of what happens with Direct Lending. However, it is possible

that if Direct Lending completely replaces ED guaranteed loans, lenders and holders will drop out of the student loan business completely.

- (3) It is likely that, if HEAL were to shut down completely, the private sector would fill this "gap" for health professions students. A good example of this can be seen with chiropractic students, who to a large extent have stopped borrowing from the HEAL program and are now financing their education through a privately run "Chiroloan" program. Given that chiropractic students tend to be the highest risk group among HEAL borrowers, the private sector's willingness to fund them strongly suggests that the remaining HEAL disciplines could obtain funding through the private sector if the need were to arise.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Number of Healthy Start Sites

Question. How many Healthy Start sites are currently being funded? Please provide for the Subcommittee comparative funding levels for FY'93, FY'94 and the FY'95 estimate.

Answer. HRSA is currently funding 15 Healthy Start sites. Awards for this program are made on the last day of the fiscal year. The sites and the FY 1992 and FY 1993 funding levels are listed below:

Grantee sites	FY 1992	FY 1993
Baltimore.....	\$ 4,647,000	\$ 6,544,247
Birmingham.....	3,845,000	1,971,716
Boston.....	4,201,500	6,472,771
Chicago.....	4,442,000	6,671,457
Cleveland.....	3,607,500	4,508,704
Detroit.....	4,296,500	4,181,517
Washington, D.C.....	3,826,500	5,493,079
New Orleans.....	3,208,500	5,443,377
New York.....	5,437,000	6,500,000
Northern Plains.....	2,873,500	3,427,968
NW Indiana.....	2,796,000	4,086,642
Oakland.....	3,460,000	5,089,975
Pee Dee Region, SC...	3,920,500	6,355,707
Philadelphia.....	4,456,500	5,752,992
Pittsburgh.....	4,652,500	5,175,849
Totals.....	\$59,670,500	\$77,676,001

Total funding for the current 15 sites will increase by 18 percent from the FY 1993 amount.

Question. Do you have any plans to expand the number of sites? If so, how many?

Answer. In FY 1994, four new projects are planned for funding, with a two year project period, for a total of \$4 million per year.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Effectiveness of Healthy Start Program

Question. HRSA runs a grant program called Healthy Start, which I understand is designed to cut the infant mortality rate in specified cities in half. Are these grants proving to be effective at reducing infant mortality in the areas where they have been tried?

Answer. The overall goal of the Healthy Start project is to reduce infant mortality in the fifteen communities by 50 percent over a five year period of program operation. It is too early to assess whether Healthy Start has attained that goal. The national evaluation of Healthy Start began in October, 1993. A team of evaluators from Mathematica Policy Research, Inc. is completing their first round of site visits in April. Information obtained from these site visits will form the basis of a process evaluation of the implementation of Healthy Start projects in the fifteen sites.

Client level data as well as vital record and Medicaid data will constitute the basis for an outcome evaluation of the Healthy Start program. All Healthy Start projects are responsible for client level data collection as of October, 1993. Vital record data will be used to assess changes over time in project area infant mortality rates.

As you know, there is often a lag time in obtaining vital record data from the states. Accessing vital record data is complicated by the need to disaggregate these data down to project area census tracts.

The evaluation of reductions in infant mortality rates must rely on comparing base line (1984-1988 average aggregate project area data) and near term (1989-1993 average aggregate project area data) rates to infant mortality rates during subsequent years. As with any other public health phenomena, trends over time will be more meaningful than a discrete year analysis.

The Healthy Start projects became fully operational in the field during FY 1994. The assessment of reductions in infant mortality will use vital record data from 1994, 1995, 1996, 1997, and 1998.

Obligations for Community Health Centers

Question. I notice that total obligations for community health centers are expected to rise in fiscal year 1995. Given our severe funding constraints, why were Federal appropriations not adjusted commensurately instead of staying constant?

Answer. Due to expanded grant funding in FY 1991 to FY 1994, changes in Medicaid eligibility and increases in Medicaid revenues, the C/MHC programs have been able to provide access to over 1 million additional medically underserved individuals since FY 1991. Based on this previous experience, we anticipate that some additional increase in Medicaid revenue will continue to occur. In addition, with the anticipated savings realized from discounted pharmaceutical prices, vaccine purchase and immunization infrastructure funding from CDC to the States earmarked for C/MHCs, we believe that health centers will be able to maintain their current service levels and serve at least the same number of patients.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

Question. The issues of health reform will necessitate a number of changes for our small rural providers. I have been pleased at the approach that the University of Washington's Community Health Services Development Program has taken with our own WAMI program. For the uninitiated, "WAMI" stands for Washington, Alaska, Montana and Idaho, and has been a unique partnership of three states without medical schools with one that has one, and it has meant a number of shared programs.

One of those programs has been the partnership with our Alaska Health Education Center (AHEC), and the work done with Alaska's (and other of the WAMI partnership's) small hospitals in strengthening them so that they will be able to survive the changes ahead. One activity, for instance, will be the community capacity building workshop at the annual meeting of the National Rural Health Association.

What programs of the Health Resources and Services Administration may be available for such an innovative program as this? Could this be funded under the Health Services Outreach Grants?

Answer. We share your regard for the University of Washington Medical School and their WAMI program. Currently we have more than a dozen active grants with the University, many of which benefit the other WAMI states directly or indirectly. Last year our funding to the University exceeded \$4 million and \$2 million to the medical school.

We also fund the Alaska Health Education Center through the University of Washington Medical School. Last year we awarded \$91,384 to the center.

Answer. Due to expanded grant funding in FY 1991 to FY 1994, changes in Medicaid eligibility and increases in Medicaid revenues, the C/MHC programs have been able to provide access to over 1 million additional medically underserved individuals since FY 1991. Based on this previous experience, we anticipate that some additional increase in Medicaid revenue will continue to occur. In addition, with the anticipated savings realized from discounted pharmaceutical prices, vaccine purchase and immunization infrastructure funding from CDC to the States earmarked for C/MHCs, we believe that health centers will be able to maintain their current service levels and serve at least the same number of patients.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CHILDREN'S MENTAL HEALTH SERVICES PROGRAM

Congress appropriated \$35 million in FY 1994 for the Children's Mental Health Services program.

Question. How are you spending that money this year?

Answer. In FY 1994, CMHS plans to spend the Children's Mental Health Services budget of \$35 million to fund four continuation grants for total of \$8.9 million and 17 new service grants for \$21.1 million. Of the 17 planned new grants, 7 have already been awarded in the amount of \$7.2 million. The remaining \$5 million will support an evaluation of service systems, a training and technical assistance center with four hubs around the country, and an education campaign to promote improved mental health for children and adolescents with serious emotional disturbances, and for their families.

DRUG ABUSE PREVENTION

Preventing drug abuse before it starts is key to long term success in resolving the drug problem. One important bellwether of prevention efforts is the Annual National High School Senior Survey. According to the 1993 survey, after a decade of steady decline, drug use among teenagers has increased. Perhaps most disturbing is the change in attitude toward drugs. The perceived dangers of nearly all illicit drugs declined at all grade levels.

Question. How do you account for this trend?

Answer. The trends from both the National Household Survey on Drug Abuse (NHSDA) and Monitoring The Future (MTF) study clearly demonstrate the significant gains made in the 1980s in educating Americans about the health risks of illicit drugs. However the lack of further significant progress regarding perceptions of risk in using illicit drugs in the 1990s indicates a need for continuing and strengthening prevention work especially among today's youth. We can never decrease our vigilance on this. These trends remind us that we must ensure we teach each generation of young people how to resist social pressure to use drugs. It is important to note though that while the increasing rates in illicit drug use among teenagers represent a reversal of the declines recorded for more than a decade, they are still well below the peak levels reached in the late 1970s and early 1980s.

There is no clear explanation for the decline in perceived dangers and the increase in drug use among teenagers. It is possible that the increases in prevalence among students may be a random interruption in the trends and a downward trend may resume in the future. Since this is the first year the trend has changed, the results should be interpreted with caution.

The shift in the trend in perceived harm in recent years is seen in data from both the NHSDA and MTF. A decrease in concern about drug abuse is also evident in data from the Gallup Poll, which showed that in 1989, 27 percent of adults reported drug abuse as the most important problem facing the Nation. By 1993, only 6 percent reported this. Social norms against use, reflected in the proportion of students in the MTF who disapprove use of these drugs, have been softening in the last year or so for marijuana, LSD, amphetamines, crack, and powdered cocaine.

A recently released SAMHSA report (Advance Report 6) discusses these trends. The report also discusses the relationship between attitudes and behavior. MTF and the NHSDA data have shown a strong

correlation between perceived harm and the likelihood of using drugs.

SUBSTANCE ABUSE TREATMENT

Some 20 percent of the nation's available drug and alcohol treatment capacity is unused. But that doesn't mean that there are enough treatment resources, because much of the unused capacity is in private programs that treat people who have health insurance. In overburdened public programs, by contrast, substance abusers are being turned away. Some areas of Iowa, for example, have a 4-week waiting period for treatment services.

Question. How many additional alcohol and drug addicts will be served with the \$310 million increase in funding for the Substance Abuse Block Grant?

Answer. The \$310 million Hard Core Initiative in the Substance Abuse Block Grant will generate up to about 34,000 additional treatment slots serving up to approximately 70,000 persons. In addition, the \$35 million Hard Core Demonstration will create about 2,000 more treatment slots, serving approximately 4,000 additional persons.

COMMUNITY EMPOWERMENT INITIATIVE

In awarding new grants, SAMHSA intends to give special consideration to applicants that serve communities with high levels of poverty. SAMHSA also intends to give further special consideration to Empowerment Zones and Enterprise Communities.

Question. Procedurally, how will this work?

Answer. SAMHSA will give special consideration to otherwise qualified applicants who propose to serve residents of places which are characterized by general socio-economic distress and which have undertaken a comprehensive strategic planning process. Further special consideration will be given to applicants who propose to serve people in areas designated as Federal Empowerment Zones or Enterprise Communities. This will be accomplished by incorporating the requirements in the criteria which will be the basis for the grant awards.

Question. Define "high levels of poverty."

Answer. The special consideration will be given to applicants serving areas with a high incidence of poverty and other forms of socio-economic distress. The Department has not established a strict rule outlining the level of poverty applicants must show before receiving this special treatment. However, it is expected that the special consideration will be given to applicants serving people in geographic areas with a significant proportion of census tracts with poverty rates of approximately 20% or higher.

MENTAL HEALTH CARE FUNDING

Question. What percentage of mental health care expenditures are financed by public funds? Breakout funding by federal, state, and local governments.

Answer. The FY 1990 national mental health care expenditures total \$42.4 billion, of which 56% percent is financed by public funds. The distribution of public funds is as follows: federal 20%, state 31%, and local 5%.

CONFERENCES

Question. How much funding is in the FY 1995 budget for conferences?

Answer. We have not established a FY 1995 budget for conferences at this time. We do not normally formulate conference plans until final appropriation levels are known, and then preliminary decisions can be made on which conferences should be sponsored in the coming year.

CHILDREN'S MENTAL HEALTH SERVICES PROGRAM

Question. For the four grants awarded with \$4,903,000 in funding for the Children's Mental Health Services Program in FY 1993, provide the number of children served, the demographic characteristics of the children, and the types and costs of services provided.

Answer. The original four five-year grants were awarded in FY 1993 to the States of Maryland, Ohio, South Carolina and Vermont. In Maryland, the target population consists of 600 individuals in East Baltimore under the age of 18, experiencing serious emotional disturbance or developmental delay, and needing service from at least two agencies. In Ohio, the population includes individuals in four counties (three are rural and the other includes the city of Canton) with a diagnosable mental health disorder and needing service from at least two agencies. In South Carolina, the population consists of 581 individuals in Charleston County who are experiencing serious emotional disturbance or impairment, over 50% of whom are African American. In Vermont, the population is made up of 7,200 individuals statewide who are experiencing serious emotional disturbance and are under age 18, except up to age 22 if in special education. Services vary among the grantees but all include systems development, training and direct services components, with an emphasis on coordination among service providers.

Question. Assess the effectiveness of services provided and the effect of the services on the utilization of hospital and other institutional settings.

Answer. It is too soon to assess the effectiveness of services provided under these five-year grants, which are in the early stages of implementation. A requirement to assess effectiveness is built into each grant and baseline data will be collected beginning this year. We expect the initial evaluation results next year.

MENTAL HEALTH CLINICAL TRAINING

Question. Provide the funding levels for the Clinical Mental Health Training Program for fiscal years 1980 to 1994.

Answer. The Clinical Training funding levels for fiscal years 1980 through 1994 are as follows:

Mental Health
Clinical Training
(Dollars in thousands)

<u>Year</u>	<u>Amount</u>	<u>Year</u>	<u>Amount</u>
1980	\$72,103	1988	\$16,755
1981	62,414	1989	12,844
1982	42,299	1990	13,534
1983	20,593	1991	13,669
1984	21,000	1992	10,835
1985	21,998	1993	2,956
1986	19,140	1994	2,500
1987	14,962		

SUBSTANCE ABUSE TRAINING

Question. Are there enough qualified substance abuse counselors in the nation?

Answer. A recently completed CSAT substance abuse training needs analysis indicated a national shortage of qualified addiction treatment professionals. Over the last two years, the epidemic of HIV infection among drug abusers in the United States, as well as the resurgence of diseases such as drug resistant TB and infectious hepatitis, has brought about the need for more counselors and a need to coordinate HIV and alcohol and other drug abuse training with State agencies, State public health agencies, public service agencies, community based organizations, and undergraduate and graduate schools.

The CSAT study indicated that in 1993, there were 58,000 alcohol and other drug abuse counselors, totalling approximately 50,000 full time equivalents. Approximately 60 percent of these counselors hold relevant degrees. The 58,000 counselors represent 40% of all professionals practicing in treatment facilities. It is estimated that 10% of these counselors leave the profession each year, requiring almost 5,000 replacement counselors per year over the next ten years, assuming that current treatment needs continue. The 1995 President's budget again requests \$8.2 million for addiction treatment training and HIV/AIDS training activities.

Question. Where is the need most urgent?

Answer. The shortage of counselors is most urgent in the rural and frontier States. This is due to the great difficulty in recruiting, hiring and paying qualified addiction specialists in these areas. There also appears to be a shortage of qualified bilingual substance abuse counselors as well.

ALCOHOL ABUSE PREVENTION AND TREATMENT

Question. Describe the alcoholism and alcohol abuse prevention and treatment programs undertaken by SAMHSA in 1993. Include a table of expenditures made for the activities reported on and the personnel used in connection with such activities.

Answer. Section 501 (e) (3) of the ADAMHA Reorganization Act (P.L. 102-321) requires the Associate Administrator for Alcohol Prevention and Treatment Policy in SAMHSA to "prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities." The data and discussion in our report will address this question in depth.

We are in the process of preparing this report. We anticipate that the report will be submitted to Congress this summer.

ADMINISTRATIVE COSTS

Question. Breakout out the administrative costs by object class for the Center for Mental Health Services, Center for Substance Abuse Treatment, Center for Substance Abuse Prevention, and the Office of the Administrator for fiscal years 1993, 1994, and 1995.

Answer. The first two tables are a display of the 1993 and 1994 administrative costs for SAMHSA by Center and the Office of the Administrator. A comparable breakdown for 1995 is not yet available since SAMHSA has not yet allocated FTE reductions. We have included the SAMHSA 1995 Congressional Justification Administrative Costs display which provides our 1995 estimate in total by object class.

Administrative costs include the costs associated with program management, as well as the costs associated with some program contracts. SAMHSA is submitting a display for the administrative costs which will not split these costs among the individual Centers and the OA for FY 1995. The 1995 President's budget requests funding for program management in total for SAMHSA and does not identify funding for salaries and expenses for individual Centers. Funding for program contracts is requested for each Center for each individual program.

(Insert SAMHSA Administrative Costs Tables)

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

ADMINISTRATIVE COSTS

1993 ACTUAL					
	CMHS	CSAP	CSAT	OA	TOTAL
Salaries (11.0).....	\$5,917,000	\$9,159,000	\$6,624,000	\$8,069,000	\$29,769,000
Personnel Benefits (12.0).....	1,036,000	1,922,000	1,448,000	1,399,000	5,805,000
Total, Personnel Compensation.....	6,953,000	11,081,000	8,072,000	9,468,000	35,574,000
Travel (21.0).....	164,000	573,000	483,000	100,000	1,320,000
Transportation of Things (22.0).....	12,000	32,000	55,000	5,000	104,000
Rent, Communications, Utilities, and Miscellaneous Charges (23.0).....	713,000	799,000	623,000	580,000	2,715,000
Printing and Reproduction (24.0).....	68,000	2,195,000	453,000	100,000	2,816,000
Other Services (25.0)	15,840,000	57,070,000	45,931,000	5,248,000	124,089,000
Supplies and Materials (26.0).....	63,000	74,000	82,000	83,000	302,000
Total.....	23,813,000	71,824,000	55,699,000	15,584,000	166,920,000

1994 APPROPRIATION					
	CMHS	CSAP	CSAT	OA	TOTAL
Salaries (11.0).....	\$7,426,000	\$10,028,000	\$7,696,000	\$9,940,000	\$35,090,000
Personnel Benefits (12.0).....	1,304,000	2,087,000	1,721,000	1,400,000	6,512,000
Total, Personnel Compensation.....	8,730,000	12,115,000	9,417,000	11,340,000	41,602,000
Travel (21.0).....	292,000	660,000	483,000	100,000	1,535,000
Transportation of Things (22.0).....	7,000	35,000	55,000	5,000	102,000
Rent, Communications, Utilities, and Miscellaneous Charges (23.0).....	790,000	790,000	641,000	697,000	2,918,000
Printing and Reproduction (24.0).....	68,000	1,824,000	250,000	100,000	2,242,000
Other Services (25.0).....	21,549,000	46,003,000	38,080,000	5,395,000	111,027,000
Supplies and Materials (26.0).....	70,000	93,000	82,000	83,000	328,000
Total.....	31,506,000	61,520,000	49,008,000	17,720,000	159,754,000

Substance Abuse and Mental Health Services Administration

Administrative Costs
(Budget Authority)

	1994 Appropriation	1994 Comparable Estimate 1/ 2/	1995 Estimate 2/	Change
Personnel Compensation:				
Full-time Permanent (11.1).....	\$31,757,000	\$31,757,000	\$31,616,000	-\$141,000
Other than Full-time Permanent (11.3)...	2,140,000	2,140,000	2,155,000	+15,000
Other Personnel Compensation (11.5).....	1,193,000	1,193,000	1,229,000	+36,000
Subtotal, Salaries.....	35,090,000	35,090,000	35,000,000	-90,000
Personnel Benefits (12.0).....	6,512,000	6,512,000	6,473,000	-39,000
Total, Personnel Compensation.....	41,602,000	41,602,000	41,473,000	-129,000
Travel (21.0).....	1,535,000	1,535,000	1,535,000	---
Transportation of Things (22.0).....	102,000	102,000	102,000	---
Rental Payments to Others (23.2).....	174,000	174,000	174,000	---
Communications, Utilities, and Miscellaneous Charges (23.3).....	2,744,000	2,744,000	2,744,000	---
Printing and Reproduction (24.0).....	2,242,000	2,242,000	2,242,000	---
Consulting Services (25.1).....	16,835,000	16,835,000	16,835,000	---
Other Services (25.2)	94,192,000	88,527,000	88,756,000	+229,000
Supplies and Materials (26.0).....	328,000	328,000	328,000	---
Total.....	\$159,754,000	\$154,089,000	\$154,189,000	+\$100,000

1/ Includes \$9.4 million for grant awards for PPWI and other programs which will be converted to contracts in FY 1995.

2/ One percent evaluation funds are not included in this estimate.

GRANTS IN IOWA

Question. Describe the CMHS, CSAP, and CSAT grants currently funded in the state of Iowa.

Answer. In FY 1993, SAMHSA funded 9 grants in the state of Iowa for a total of \$14,288,358. The grants are listed below:

CENTER FOR MENTAL HEALTH SERVICES (Total \$2,713,965)Community Support Program

Grant Number: H5SM48140

Title: Iowa's Enhancement of Community Support for Persons With Serious Mental Illness

Grantee: Iowa Department of Human Services
Location: Des Moines, Iowa

FY 1993 Amount: \$25,708

Description: Supports activities sponsored by the Iowa Coalition and the State Alliance for the Mentally Ill (AMI). The Coalition is a consumer group which offers presentations by outreach coordinators, distributes Coalitions brochures, and supports part time peer counselors and peer consultants. The State AMI supports family education, training for AMI members, and consulting to agencies and training centers.

Mental Health Block Grant Set-Aside

Grant Number: H1SM46201

Title: Mental Health Data Collection System - Iowa (Mental Health Statistical Improvement Program)

Grantee: Iowa Department of Human Services
Location: Des Moines, Iowa

FY 1993 Amount: \$94,598

Description: Provides technical assistance to State mental health agencies for implementation of uniform, integrated mental health data collection systems.

Protection & Advocacy

Grant Number: SMX199700-93-0

Grantee: Iowa Protection and Advocacy Services, Inc
Location: Des Moines, Iowa

FY 1993 Amount: \$246,472

Description: Strengthens State programs which ensure that the rights of mentally ill individuals are protected while they are residents of in-patient facilities and for 90 days following their discharge.

Projects for Assistance in Transition from Homelessness (PATH)

Grant Number: SMX060016-93

Grantee: Iowa Department of Human Services
Location: Des Moines, Iowa

FY 1993 Amount: \$300,000

Description: Provides services to persons who are homeless and have serious mental illnesses, including those with a co-occurring mental illness and substance use disorder.

Mental Health Block Grant

Grant Number: 93B1IACMHS

Grantee: Iowa Department of Human Services
Location: Des Moines, Iowa

FY 1993 Amount: \$2,047,187

Description: Provides funds to support mental health prevention, treatment and rehabilitation services.

CENTER FOR SUBSTANCE ABUSE PREVENTION (Total \$1,108,245)

Pregnant Women and Infants Program

Grant Number: SPO-02754

Grantee: House of Mercy
Location: Des Moines, Iowa

FY 1993 Amount: \$739,996

Description: Pregnant and Postpartum Women and their Infants Programs are designed to develop innovative, community-based models for the coordination of service systems for linking health and promotion and treatment services for substance abusing pregnant women and their young children. The House of Mercy program is a major residential substance abuse program which actively guides substance abusing women through treatment programs while caring for the infants and children.

Community Prevention Program

Grant Number: SPO-03204

Grantee: United Way of East Central Iowa
Location: Cedar Rapids, Iowa

FY 1993 Amount: \$368,249

Description: Community Partnerships are system-oriented efforts designed to assist communities in developing comprehensive, coordinated prevention initiatives responsive to local needs. The Substance Abuse Free Environment (SAFE) Coalition, led by the United Way of East Central Iowa, was formed in 1989 and has 16 partners representing a broad spectrum of the community. Its mission is threefold: to increase awareness of substance abuse in the community; to encourage a grassroots, community that will not tolerate a diminished quality of life due to substance abuse; and to serve as a catalyst for interagency and intergovernment cooperation among treatment and prevention organizations.

CENTER FOR SUBSTANCE ABUSE TREATMENT (Total \$10,466,148)

Criminal Justice/Critical Populations Programs (Co-funded)

Grant Number: TI00247-03

Grantee: Center for Alcohol and Drug Services, Inc.
Location: Davenport, Iowa

FY 1993 Amount: \$696,651

Description: This project proposes to train juvenile justice and human service professionals in substance abuse, initiate formal screening for substance abuse in the juvenile justice system, develop a day treatment program for 12 youth and families, enhance an existing residential program for 16 substance-abusing delinquent youth, develop an intensive aftercare program with a minority outreach and support component, initiate case coordination for risk youth, develop a cross-agency staff exchange between the Center and Juvenile Court Services, and initiate child care and transportation services for youth in substance abuse treatment. Day treatment represents both an enhancement and creation of new capacity. All proposed enhancements will be integrated with existing programs and services provided by the substance abuse, human services, juvenile justice, health, mental health, and educational systems in the community, with the result being a comprehensive, integrated constellation of services to targeted youth and their families.

Substance Abuse Block Grant

Grant Number: B1 IASAPT-01

Grantee: State of Iowa, Department of Public Health
Location: Des Moines, Iowa

FY 1993 Amount: \$9,769,497

Description: This formula grant program supports prevention and treatment services for alcohol and other drug abuse.

AIDS FUNDING

Question. Breakout the AIDS funding in SAMHSA.

Answer. The FY 1995 President's budget for AIDS is as follows:

HIV/AIDS Budget for FY 1995

Center for Mental Health Services.....	\$4,443,000
Center for Substance Abuse Prevention..	1,000,000
Center for Substance Abuse Treatment...	26,822,000
Program Management.....	<u>721,000</u>
Total.....	32,986,000

Question. What percentage of SAMHSA's AIDS budget is spent on AIDS prevention?

Answer. In FY 1994, the estimate for funds spent on AIDS prevention activities is 16.6 percent.

Question. What percentage of the Center for Mental Health Services AIDS budget is devoted to prevention?

Answer. All of the \$4.4 million for AIDS training and demonstrations is devoted to prevention. Of this amount, 25% is for primary prevention which is used to decrease the incidence/prevalence of the disorder. The remaining 75% is devoted to secondary prevention which provides adequate treatment so that the disorder does not become worse.

CAPACITY EXPANSION GRANTEES

Question. Provide a list of current Capacity Expansion grantees showing the amount of the grant and a summary of the grant's purpose.

Answer. The Capacity Expansion Program was designed to expand treatment services in the areas most in need of additional capacity. Applicants were required to demonstrate a shortage of treatment capacity in areas that had a high incidence and prevalence of drug abuse. A total of 40 projects were supported by the 35 grants awarded in FY 1993. (See list of grants attached.)

CAPACITY EXPANSION/HARD CORE INITIATIVE

Question. Is the population targeted by Capacity Expansion grantees significantly different from the hard core users targeted with the \$310 million increase in the Substance Abuse Block Grant?

Answer. The Hard Core Initiative targets individuals who have been most resistant to treatment and/or least successful in abstaining from drug use following treatment. Hard Core targets our most challenging clients. The Capacity Expansion Program was designed to expand the overall availability of drug treatment services in areas of need as identified by the States. In general, CEP created new capacity to serve a broader range of our target populations.

**Center for Substance Abuse Treatment
Capacity Expansion Grant Awards
FY 1993**

GRANT #	ORGANIZATION	STATE	AMOUNT
00284-01	Guadenzia	PA	\$438,119
00293-01	U. of Med. & Dentistry of NJ-Piscataway	NJ	408,853
00295-01	TRI-COUNT	SC	433,551
00297-01	Minority Alcohol and Drug Rehab	RI	372,486
00298-01	Seven Counties Services, inc	KY	260,609
00299-01	York County Shelters, Inc	ME	326,214
00305-01	Skomish Indian Tribe	WA	182,023
00307-01	Alice Counseling Center	TX	212,000
00310-01	Alaska Women's Resource Center	AK	500,000
00312-01	Northeast Treatment Centers	DE	334,355
00313-01	APT Foundation, Inc	CT	408,430
00314-01	Covenant House/under 21	NY	330,400
00314-01	Project Return Foundation, Inc.	NY	571,814
00314-01	Week-End Center, Inc	NY	302,681
00315-01	Gateway Community Services, Inc	FL	384,436
00319-01	Nevada Treatment Center	NV	310,636
00321-01	Tift County Mental Services	GA	385,143
00324-01	Chestnut Health Sevice, Inc	IL	316,666

**Center for Substance Abuse Treatment
Capacity Expansion Grant Awards
FY 1993**

GRANT #	ORGANIZATION	STATE	AMOUNT
00324-01	Central East Alcoholism and Drug Council	IL	\$387,410
00325-01	The Greater Kansas City Foundation	MO	410,706
00327-01	Self Help Addiction Rehabilitation	MI	744,945
00327-01	Project Rehab	MI	326,503
00329-01	Pascus Yaqui Tribe	AZ	216,139
00329-01	Chicanos Por La Causa, Inc	AZ	329,298
00331-01	WI Dept of Corrections	WI	152,190
00332-01	NOVA House Association, Inc	OH	402,515
00333-01	University Of Minnesota	MN	197,139
00335-01	Pueblo Treatment Services, Inc.	CO	541,898
00336-01	Turquoise Lodge	NM	695,929
00338-01	DCCA, Inc	KS	407,223
00338-01	NED/A Referral and Tracking Station	KS	192,525
00339-01	Gateway House, Inc	AR	145,808
10295-01	Charleston Co Substance Abuse Commission	SC	497,578
10310-01	Akella House, Inc	AK	261,518
10310-01	Cook Inlet Tribal Council. Inc	AK	343,549
10312-01	Connections CSP, Inc	DE	550,150
10313-01	CT Dept of Correction Addiction Svcs	CT	400,000
10314-01	Inwood Community Services, Inc	NY	149,500
10327-01	Metro East Substance Abuse Treatment Corp	MI	464,000
10338-01	KS Multicultural A & D Treatment Center, Inc.	KS	306,742
TOTAL			\$14,601,681

PREVENTION BUDGET

You can't treat your way out of an epidemic. Prevention is essential and good models are available.

Question. Why does the President's budget provide level funding for CSAP's budget?

Answer. The key to long term success in resolving the drug problem is preventing drug use and abuse. However, neither prevention nor treatment alone can produce the desired result of reducing substance abuse. To reach the hard core user, for example, we are proposing an intensive treatment approach. SAMHSA is requesting \$345 million to devote to reaching this group through new block grant and demonstration funding in FY 1995.

At the same time, the FY 1995 request will provide CSAP nearly \$76 million in funding for new programs, including almost \$21 million for a new women's initiative, due to the scheduled completion of Federal support for 5-year grants awarded in 1990. Funding for new grants will be used to focus on the highest risk populations in the most severely affected areas. While the total CSAP request

reflects level funding, we feel substantial progress can still be made in this area.

DELAYED OBLIGATIONS

Question. How does SAMHSA intend to implement the administration proposal to delay \$82,200,000 in obligations in the FY 1995 budget?

Answer. Obligations will be delayed in the Substance Abuse Block Grant which totals \$1.4 billion. Historically, 50 percent of the Block Grant funds are not expended until the following fiscal year and 50 percent are expended in the current year. In FY 1995, therefore, delaying \$82 million in obligations will require delaying \$41 million in outlays, which would reduce outlays by an additional 6 percent. This is not expected to have a significant impact on the States. We do not believe this minimal deferral will be of concern to them, especially if it allows us to provide a larger total increase for substance abuse programs.

OTHER SERVICES

Question. Describe what the \$24,842,000 increase in "other services" on page 11 of SAMHSA's justification will be used for.

Answer. In 1995, SAMHSA is supporting several new initiatives that will result in a \$24.8 million increase in contractual services. Of this increase, \$9.3 million is for new funding from the 3 percent set-aside requested for the Hard Core Initiative in the Substance Abuse Block Grant Program. The remaining \$15.5 million is a reallocation of SAMHSA grant funds into contractual services. This includes the restoration of the \$7.5 million FY 1994 State grant earmark back to the block grant set-aside, and another \$8 million in conversion of grants to contracts. Of the \$24.8 million increase, \$7.8 million will be used for the programmatic expansion of a women's prevention initiative, \$14.5 million will be used to fund technical assistance efforts that support the Substance Abuse Block Grant Program, and \$2.5 million will be used to increase data collection efforts which will focus on Health Care Reform issues.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

FUNDING FOR MENTAL HEALTH AND DRUG ABUSE PROGRAMS

Most estimates indicate that the direct and indirect costs of mental illness are more than twice those of drug abuse. The FY95 Budget proposed level funding for mental health programs in SAMHSA, and a \$345 million increase for drug abuse programs.

Question. How do you explain the disparity between the cost of these illnesses and the proposed funding levels?

Answer. This year is one of difficult choices and limited new investment funding. The FY 1995 President's Budget reflects the high priority placed by the Administration on increasing treatment services for the hard core population as articulated in the National Drug Control Strategy. The Hard Core Initiative targets individuals who have been most resistant to treatment

and/or least successful in abstaining from drug use following treatment, representing one of the most costly group of drug users to society as a whole. The National Drug Control Strategy has concluded that hard-core users are fueling the overall demand for drugs and are disproportionately affecting crime, violence, and HIV/AIDS transmission in our cities.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

NATIVE AMERICANS AND ALASKAN NATIVES

With respect to the Alcohol and Drug programs, I would like to express my concern about this Administration's set-aside for "hardcore" drug use. In Alaska, our "hardcore drug of choice" is alcohol. Rural populations more frequently have problems with abuse of alcohol than they do cocaine, heroin, IV drug users, or gang related drug usage.

If the projected increase in the President's budget is planned to be distributed with the block grant, there must be a method for rural states to be able to spread this money out to rural areas and not concentrate resources in a few large communities. In the remote areas of my state, for instance, there is a significant problem with abuse on inhalants.

These inhalants are not controlled substances in the village -- typically the fuel used in the village to heat homes is the same fuel used for any number of other purposes, including filling the tanks of the vehicle which will help to transport the food which they hunt.

There needs to be some acknowledgement in the block grant formula, or in a separate system, that it is more expensive to serve rural remote populations. These costs include transportation for staff and client, poor weather, low populations, higher cost of living, and staff salary costs.

Our State Division of Alcohol and Drug Abuse tells me that their most significant unmet needs are additional resources on an ongoing basis to women of childbearing age and dually diagnosed patients.

Alaska's rate of fetal alcohol syndrome is 0.5 per 1,000 births, but in the Alaska Native community this is as high as 5.2 per 1,000 live births. The national average is 0.22 overall, and 4.0 for Native Americans nationwide.

Question. Are there additional resources which could be dedicated to these populations without resorting to categorical grant funding?

Answer. The Hard Core Initiative would provide funds to all States, including Alaska, using the current Block Grant formula. The State would have the flexibility to allocate these resources to rural areas rather than large communities if desired. Beyond block grant funding, there is no additional CSAT categorical funding which could be dedicated to the population of Alaskan Natives. However, under an intra-agency agreement with the Indian Health Service (IHS), CSAT and IHS will continue to work together to

expand effective addiction treatment services for American Indians and Alaskan Natives. In addition, five projects under the CSAT's Rural, Remote and Culturally Distinct program will receive continuation funding in FY 1995. Four of the projects are targeted for Native Americans (The Navajo Nation of Arizona, the State of Alaska, Inter-Tribal Council of Michigan, and the Kickapoo Tribe of Texas) and the fifth project is for migrant populations in Texas.

HARD CORE SUBSTANCE ABUSE/DUALLY DIAGNOSED POPULATION

Question. Could the dually diagnosed population be included in the definition of "hard core" substance abuse?

Answer. The dually diagnosed are included, to the extent they meet the definition of "hard core" substance abuser. Although the definition of "hard core" substance abuse has not been decided at this time, individuals who are "dually diagnosed" could be targeted for treatment with these grant funds. "Dually diagnosed" can mean individuals who abuse alcohol and drugs or individuals with mental illnesses and co-occurring alcohol and drug use. Research shows the major damage alcohol abuse causes in our society as the drug of choice for many, as well as its role as a gateway to other drugs. Dually diagnosed drug abusers are among the most vulnerable and hard to treat. Since the focus of the "hard core" initiative is to provide treatment for the most treatment-resistant segment of the population, the dually diagnosed are a very appropriate sub-population to receive support from this initiative.

PREVENTION SERVICES FOR HARD CORE USERS

Question. Lastly, could states be provided the latitude to use some of the increased funding to provide prevention services in areas with significant "hard core" users?

Answer. The proposed legislation for the Hard Core Initiative targets all of the hard core funds for treatment services only; however, States will have the flexibility to use their basic Substance Abuse Block Grant funds for this purpose.

HEALTH CARE FINANCING ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RURAL HOSPITALS

Mr. Harkin: How is Medicare supporting the needs of rural hospitals in the wake of cutbacks in research and demonstration funds for rural hospital projects?

Mr. Vladeck: HCFA's request would reduce funding for Rural Health Care Transition Grants (RHCTG) in FY 1995 to \$7 million. Because we had to make some tough choices within budget constraints, funds were redirected to a promising new program--HCFA's State Rural Health Network Reform Initiative. This program will help States address rural health issues within the context of comprehensive statewide health reform. This supports HCFA's

goal to promote area-wide health reform. We are increasing this program's funding from \$1.7 million in FY 1994 to \$7.7 million in FY 1995. Our request for \$7 million for RHCTG will allow us to provide enough money so that most grantee organizations can continue with their most important plans.

The RHCTG program was only the starting point to assist small rural hospitals to improve their financial position. Enhanced Medicare payments are also made to sole community hospitals, rural referral centers, and Essential Access Community Hospitals/Rural Primary Care Hospitals. Therefore, individual rural hospitals should have sufficient funds from regular Medicare payments to carry out projects similar to those funded under the RHCTG program.

Since enactment of the RHCTG program in OBRA 1987, rural hospitals have received substantial increases in Medicare program payments. Under current statute, they will be paid at a base rate that is equivalent to that for urban hospitals, beginning in FY 1995.

MEDICARE TRANSACTION SYSTEM

Mr. Harkin: The Health Care Financing Administration has begun a major automated system development effort to improve processing Medicare claims. Its Medicare Transaction System, which will cost over \$150 million, is expected to generate administrative savings, help detect fraudulent claims and help to eliminate erroneous payments. How will the system achieve these savings?

Mr. Vladeck: Administrative savings will be achieved through consolidation and standardization.

Economies of scale will lower the overall cost of ongoing claims processing. The cost of maintaining, enhancing and implementing changes will be significantly reduced because these changes will only be made to one system, rather than to the 14 different systems now in use. The MTS will eliminate the duplication in our present systems, both internal to intermediary and carrier operations and between intermediaries and carriers and our Common Working File system. Program changes, including those designed to counter real billing problems, can be implemented easier and quicker. Additionally, MTS operating site contracts will be regularly re-competed to assure that the lowest possible processing price is obtained.

Through electronic bill/claim submission using national standard telecommunications protocols, speeds, codes and software drivers, claims processing will be standardized. The specifications are currently being developed by a joint HCFA/industry task force. Electronic coordination of benefits among Medicare, Medicaid, Medigap and supplemental payers will be simpler and more efficient for all payers when these standardized specifications are implemented.

Standardization will result in better data quality, which will assist in the discovery of fraudulent billing patterns. The flexibility of MTS will allow edits to be added to screen out before payment claims with characteristics found to be suspect. The combination of Part A and Part B payment data will allow a more accurate assessment of whether services or items have been billed more than once by related providers, avoiding duplicate payments. All claims data, regardless of type of claim (for example, inpatient, physician, etc.) will be available at the time a claim is processed rather than after it is paid, as is sometimes the case today. New software would enable investigators to discover more sophisticated billing patterns involving multiple related providers, related procedures, etc. Control of edits at the operating sites and better claims audit trails will prevent the suspension of edits by local contractors, thus avoiding payment of fraudulent claims for which there are preventive edits. A national provider file will allow the uniform imposition of administrative sanctions, pre-payment review, and suspended payments.

The MTS will also help to eliminate other types of erroneous payments. Improved data quality, through standardization of coding, editing, etc., will allow more accurate processing of claims both by the MTS operating sites and by medical reviewers at local contractors. Access to more complete beneficiary data, for example, both Part A and Part B data, will also allow more accurate processing, since a beneficiary's total treatment can be taken into account. The MTS will produce better data on patterns of abuse, including use of services or items that are not likely to be medically necessary, so that edits can be devised which will cause the claim to except for manual review or to be denied. The MTS will be able to handle more complex claims for beneficiaries with multiple diagnoses. Use of a uniform system will allow better evaluation of the effectiveness of individual medical review screens. Pricing for services or items, for which there is not a local price, will be available to the intermediary and carrier, promoting uniformity in prices among them for new services or items or for those for which there is a low incidence.

Mr. Harkin: What impact will this new system have on the role and staffing of Medicare contractors?

Mr. Vladeck: During the design phase, there should be no effect on carrier and intermediary personnel. As part of the design phase, we are working to develop staffing plans for implementation of the Medicare Transaction System. After implementation, which is expected to be completed by 1999, the Medicare Transaction System may have some effect on personnel levels at current contractors and on the skill mix of those employees. There will be fewer data processing jobs, but more jobs in customer service areas, medical review, fraud and abuse, etc.. The length of the design and implementation period should allow sufficient time for us to work with our contractors to plan how they will accomplish this change.

We anticipate that the fiscal intermediaries and carriers will remain the first point of contact for providers and beneficiaries in all activities related to claims processing. These local contractors will be responsible for all customer service activities, appeals, to name a few of their functions. Where automated systems are required to perform these functions, the MTS will replace their own systems.

Mr. Harkin: What are the total costs and administrative and program savings associated with this initiative?

Mr. Vladeck: The \$150 million is the original estimate for the total costs of implementing MTS including the MTS Design contract (the contract to design and build the system), the MTS Independent Verification and Validation (IV&V) contract (the contract to assist HCFA in monitoring, verifying and validating the design and building effort) and the transition of current systems to MTS. The cost of the recently awarded 6-year contract, will be \$19 Million. The IV&V contract has not yet been awarded, hence the cost has not yet been determined; but is expected to be less than the MTS Design contract. The significant portion of costs (over \$100 million) was the estimate for implementation and transition to MTS. The costs are not expected to be revised until the design of the system is known; now scheduled for mid to late CY 1995.

We estimate average annual administrative savings of \$200 million a year after full implementation. Savings will begin to be realized in FY 1997 (approximately January, 1997) as the MTS is installed and contractors are converted. In addition to the average \$200 million per year administrative savings after full implementation in FY 1999, we believe that the MTS will have a positive effect on our ability to monitor and manage Trust Fund outlays. The MTS will ensure uniformity in the claims editing and pricing process, thus reducing the possibility of variations in payment and coverage determinations. In addition, the MTS will improve the Health Care Financing Administration's ability to implement new methods or rules of payment, analyze data and detect possible fraud and abuse on the part of health care providers.

Mr. Harkin: How will you evaluate the anticipated benefits of this system when it is operational, and how often will an evaluation be performed?

Mr. Vladeck: Some benefits of MTS will be easier to evaluate than others. For example, an aspect such as "less cost" can be measured by comparing the cost of claims processing before and during the two year implementation period. Another aspect, such as "more uniformity" will mostly depend on provider and beneficiary satisfaction and, therefore, some type of survey or "customer satisfaction" indicator will need to be developed. It has been, and remains, HCFA's intent to involve the beneficiary and provider communities in all phases of the project, including assisting in development of requirements and indicators of

success. Plans to involve beneficiaries and providers are now being finalized.

HCFA plans to implement several evaluations during all phases of the project, and after the project is fully completed. We have developed numerous "critical success factors" already and will expand the list once all of our partners (the intermediaries and carriers) and our customers (the beneficiaries and providers) are fully involved in the project.

PRICING OF DURABLE MEDICAL EQUIPMENT

Mr. Harkin: The Health Care Financing Administration has taken a major step toward reducing improper expenditures for Durable Medical Equipment (DME) by having 4 Regional carriers process all DME claims. These carriers, servicing specific geographic areas, should be in the best position to know reasonableness of prices charged for DME in their areas.

However, the carriers do not have the authority to set reimbursement rates for DME based on what they determine to be fair and reasonable cost for each item. Only the Secretary can make that determination.

How often has the Secretary used her power to set reasonable Medicare payment rates for durable medical equipment?

Mr. Vladeck: OBRA 87 prohibited all inherent reasonableness decisions affecting DME payment amounts until 1991. This power has gone essentially unused since 1991 because the same provision created a burdensome process for changing DME payment amounts based on the Secretary's inherent reasonableness authority. However, we are currently in the process of developing a final regulation on payment limits for home blood glucose monitors.

Mr. Harkin: Wouldn't it be to the Government's advantage to delegate pricing for medical equipment to the carriers? If not, why not?

Mr. Vladeck: Despite numerous improvements in the way we pay for durable medical equipment, the bottom line is that too often Medicare is still not getting the best prices available.

We believe that the most effective and efficient way to get the best DME prices available is through competitive bidding for DME, as we have proposed in the Health Security Act. Competitive bidding would allow the Federal government and Medicare beneficiaries to rent or buy DME at a fair market price.

Under our proposal, competitive bidding would be conducted at the local level, ensuring that DME prices reflected legitimate variations in local DME costs. Studies of other Federal and State health programs indicate that competitively bid services can save taxpayers and beneficiaries money, without compromising quality of care or access.

However, we also realize that competitive bidding may not be cost-effective for all DME items or in all areas. In such cases, restoration of carriers' inherent reasonableness authority may be advantageous. For DME other than high-volume, high-cost items which lend themselves to competitive bidding, we believe the carriers are in a good position to make inherent reasonableness determinations efficiently and to respond to local problems with payment amounts. The carriers can both detect and address problems with individual items where the local payment amount is either grossly excessive or deficient. The carriers had authority to use inherent reasonableness for DME prior to OBRA 87, and currently have this authority for other non-physician items and services.

Mr. Harkin: Does the Secretary have authority to delegate her power to adjust Medicare payment rates for equipment to the regional carriers, or would this require legislation?

Mr. Vladeck: No, the Secretary does not have authority to delegate this power.

Prior to OBRA 87, the carriers had authority to make inherent reasonableness decisions for DME, prosthetics, and orthotics. OBRA 87, however, prohibited all inherent reasonableness decisions for these items until 1991. Effective 1991, the use of inherent reasonableness for these items was limited to the Secretary under a set of complex and burdensome rules that had previously applied only to physician services.

We believe legislation would be necessary to allow the carriers to adjust current fee schedule amounts that are either grossly deficient or excessive.

FUNDING FOR PAYMENT SAFEGUARDS

Mr. Harkin: I have introduced a bill, S. 256, that would provide the administrative funds necessary to ensure that Medicare claims are paid properly as Medicare's claims workload increases each year. My bill would be identical to the budget rules already enacted for the Internal Revenue Service, and I understand your agency requested OMB approval of a similar funding mechanism for fiscal 1995.

Can you tell us what merit you see in legislation of this type, and why OMB did not favor it?

Mr. Vladeck: To the extent that this type of legislation would help stabilize Medicare contractor funding in general, and Payment Safeguard Funding in particular, this action deserves serious consideration. However, we view this type of fix as short term in nature. Realizing that we must continue to maintain a sentinel effect to protect the Trust Fund, HCFA's long term goal is to effectuate changes in the processing, policy, and systems arenas to assure that claims are submitted, processed, and paid correctly initially. As we continue to make strides in this area,

we will continue a dialogue with all parties in an effort to assure that Payment Safeguards is funded to the fullest extent possible.

The FY 1995 Budget defers all legislation which is not directly related to Health Care Reform.

Mr. Harkin: Isn't this the kind of proposal that ought to be considered as part of "reinventing government", where every dollar spent actually saves 14 times as much through better auditing?

Mr. Vladeck: Yes, this is the kind of proposal that deserves serious consideration, especially in light of "reinventing government". Safeguarding the Medicare Trust Fund is of paramount importance and any proposals to assure funding for this effort should be given serious consideration.

MEDICARE/MEDICAID COVERAGE DATA BANK

Mr. Harkin: You requested a \$15 million supplemental to implement the Medicare/Medicaid Coverage Data Bank, which was mandated by the 1993 reconciliation legislation. I have been contacted by employer groups who oppose implementation of the data bank on the grounds that it imposes an enormous paperwork burden on businesses, and duplicates existing efforts to insure that Medicare and Medicaid benefits are paid only as a last resort, after checking private health insurance. Are you working with employer groups to resolve their concerns about the Data Bank legislation?

Mr. Vladeck: We have been working with employer groups to implement the Data Bank in the least burdensome manner. In January, HCFA sponsored two conferences for employers at which we discussed Data Bank issues and how they could be resolved. We shared initial recommendations with an industry focus group and considered their comments in preparing our preliminary guidance.

HCFA continues to meet with employer representatives. We plan to publish preliminary Data Bank guidance in the Federal Register very soon. The notice will include our recommendation that Congress enact an 18 month delay in the implementation of the Data Bank. This action will afford HCFA an opportunity to analyze how the Data Bank will operate within the context of health care reform and how to more effectively minimize the employer burden.

Mr. Harkin: If you don't get a supplemental appropriation, how would you propose to implement the Data Bank program?

Mr. Vladeck: In the absence of a Congressional delay in the implementation of the Data Bank, and without additional Fiscal Year 1994 funds to support immediate implementation, HCFA will be forced to re-examine our existing priorities and make hard decisions on which programs and priorities should be funded.

EXTRAVAGANT SPENDING BY HOSPITALS

Mr. Harkin: Last fall I held a hearing to highlight extravagant expenditures of Medicare funds by hospitals and corporate offices for such items as alcoholic beverages and entertainment costs. As a result of this hearing, I am pleased to say that you revised your regulations to specifically disallow Medicare payments for alcoholic beverages, charitable contributions and lobbying activities. This was a good beginning. Do you plan to adopt more stringent guidelines to prevent abuse of Medicare funds in such areas as entertainment, foreign travel, scholarships for children of executives, and memberships in civic organizations?

Mr. Vladeck: Yes. We are continuing to review GAO and IG recommendations to determine what areas need further clarification. Specifically, staff is analyzing the contractors' working papers which explain specific payments to hospitals. This will result in further changes and clarifications to our Carrier Manuals.

TARGETING OF MEDICARE SURVEY AND
CERTIFICATION FUNDING

Mr. Harkin: Your budget includes \$141.8 million to survey more than 20,000 facilities that must be recertified annually on quality of care in order to participate in the Medicare program. Yet many of these facilities have an outstanding record of quality care, and may not need annual inspections, while other facilities may merit much more frequent inspections. Would you favor legislation giving you authority to target survey and certification activities more frequently on those facilities that have a track record of substandard care, with fewer inspections of those facilities that seldom have deficiencies?

Mr. Vladeck: Without knowing the specifics, I can't comment definitively but we have investigated targeting our resources in survey and certification. Consistent with the recommendations advanced by Vice-President Gore and the Report of the National Performance Review, we are continually looking to improve our programs to insure quality of care. We would certainly welcome the flexibility to focus in on those facilities that we believe are more likely to have significant problems.

Mr. Harkin: How often do you need to survey most home health agencies, which are relatively safe?

Mr. Vladeck: We are required by law to inspect home health agencies annually. As we re-examine HCFA's future program needs, we may wish to examine our policy regarding the frequency with which we inspect home health agencies with an eye towards surveying those agencies with a good record of compliance with Medicare quality standards less frequently than under current law,

in the absence of a complaint about care or cause for concern. This would require a change in the Social Security Act. Those agencies with a record of problems need to be inspected at a minimum annually and in many cases even more frequently.

We are closely examining home health survey schedules and we will work with Congress to ensure the health and safety of these beneficiaries.

Mr. Harkin: How much would be saved if you only had to survey home health agencies once every two years?

Mr. Vladeck: We estimate that in FY 1995 we will spend over \$33 million surveying 100% of the home health agencies. If we survey all home health agencies every two years and perform all the complaint and follow-up inspections as well as focused inspections of problem agencies, the \$33 million level would be reduced by \$6 to \$10 million.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER BOND

RISK ADJUSTMENTS FOR ENROLLEES IN MANAGED CARE PLANS

Mr. Bond: Many of the health care reform proposals that would encourage more Americans to be enrolled in managed care plans recognize the need for rates to be "risk adjusted" in order to prevent health plans from becoming financially unstable because of adverse risk selection. That is, plans that attracted a disproportionate share of high risk enrollees but received only average rates for them would be placed at a much greater financial risk. Effective risk adjustment also significantly reduces any incentive for insurers to game the system by risk selection strategies like selective marketing.

My understanding is that most of the research in risk adjustment which HCFA has sponsored to date is devoted to risk associated with the health needs of the elderly. Little or none has been devoted to the needs of children.

Would you please report to the subcommittee what research, if any, HCFA either has sponsored or plans to sponsor to develop risk adjusters specifically for children, including high risk children with birth defects.

If HCFA has not sponsored research on risk adjustment for children, would you provide the subcommittee estimates of the federal investment that would be required to bring the development of risk adjusters for children in par with the current state of the art of risk adjustment that has been developed for elderly health plan enrollees?

Mr. Vladeck: The Office of Research and Demonstrations (ORD) is currently sponsoring a project to develop a Medicaid risk adjustment system for States that are interested in capitation. The investigators are considering age groupings for risk

adjustment purposes, which will create separate risk categories for children. In addition, we are currently soliciting for the development of both near-term and long-term risk adjustment systems for the under-65 population. These projects will consider risk adjustment for children. Finally, the current ORD grants program announcement specifically solicited for projects on risk adjustment development for children.

HCFA anticipates sponsoring some research related to risk adjustment for children, if not through a specific project, then indirectly through work on the under-65 population.

Mr. Bond: What are the plans for HCFA to invest in development of risk adjustment in response to the President's health care reform proposal which would require federally established risk adjustment methodologies to reflect risk associated with age, sex, health status, and other indicators? Does the administration intend to develop risk adjusters specifically for children?

Mr. Vladeck: We agree that risk adjusters, including pediatric risk adjusters, are a very important component of health reform. Children with special needs comprise a unique group with a variety of cost profiles. HCFA is preparing a research strategy for developing risk adjustment systems for the population under age 65, including children. In addition, our grants program announcement, mentioned above, was developed with health care reform needs in mind. This program will call for new risk adjustment studies, and additional research may be funded through special solicitations.

Under the Health Security Act, the National Health Board will develop risk adjustment methodology. All age groups, children included, will be considered in developing this methodology. Other factors that will be taken into account include health status, geographic area of residence, and socio-economic status.

Mr. Bond: HCFA is approving more and more waivers to States to enroll Medicaid recipients in managed care. Since half of all Medicaid recipients are children, these managed care waivers have special implications for children, particularly children with special health care needs. How does HCFA require States to address risk adjustment for children when the States receive approval to enroll Medicaid recipients in capitated managed care plans?

Mr. Vladeck: States receive approval to enroll Medicaid recipients in capitated managed care plans through 1115 demonstrations, freedom-of-choice waivers, and in the regular Medicaid managed care programs.

For section 1115 demonstrations, HCFA does not impose specific requirements on the States in term of risk adjustment. The States' payment methodologies are reviewed for adequacy and appropriateness. Some States' methodologies include risk adjustment and others do not. As part of an overall evaluation

of the section 1115 State health reform demonstrations, HCFA will be examining the impact of each State's payment methodology on the managed care plans and their enrollees (including populations with special needs), as well as comparing methodologies across States.

In most current Medicaid managed care plans with risk-based contracts -- health maintenance organizations, health insuring organizations, and prepaid health plans -- risk adjusters are limited to the more traditional rate adjustments such as age and gender. Rates specific to these categories recognize the varying degree of risk associated with a particular age or gender category, e.g., newborns to age 1, or women of child-bearing age.

Some prepaid contracts include specific rates for enrollees with certain conditions, such as pregnant women or those identified as HIV positive. Other contracts include specific provisions to limit the contractor's risk on either an individual or aggregate basis. These arrangements may cap a plan's risk at a preset amount for the cost to the plan for any enrollee's medical care, or may cap the plan's total potential losses under the contract with the State.

With respect to the enrollment of children in capitated managed care plans, the use of age-based adjustments help to make the rates more accurate for this vulnerable population. In addition, we have suggested that States can make an adjustment to their capitation rates to acknowledge the cost of EPSDT targets not included in the base year on which rates are determined, like is being done in Wisconsin.

We have not, however, imposed special requirements on States regarding risk adjustments before permitting mandatory enrollment in managed care plans. We have required that capitation rates be actuarially sound and not in excess of the upper payment limit, in accordance with the applicable regulations. We believe that concerns for potential under service for children or other enrollees are better addressed as quality of care issues. States must demonstrate that access to care for all populations covered under one of these programs not be substantially impaired and that the quality of care be clearly demonstrated through quality assurance mechanisms and monitoring of the program.

MEDICARE/MEDICAID COVERAGE DATA BANK

Mr. Bond: The President's budget includes \$80 million to implement the Medicare/Medicaid Data Bank authorized in OBRA 93. The Data Bank was conceived to eliminate Medicare secondary payer problems and the data on private coverage in the Data Bank is to be derived, in part, from a new insurance W-2 form. It is well recognized that this is not a workable method to determine whether a Medicare beneficiary might have private insurance. The W-2 form would only be collected once a year, yet in the private sector, 7,500,000 coverage changes occur each month. The data in the Data Bank will be out of date before it is even entered.

What plans does HCFA have to propose changes in the Data Bank to

make it workable. Are you aware of the Health Information Modernization and Security Act introduced by myself and Senator Riegle which would standardize billing and financial transactions under both federal and private sector health programs? This proposal would, among other things, create a private sector operated "uniform working file" system that would perform the same functions the Data Bank was envisioned to perform, but do so in a way that is efficient, cost effective and will contain accurate and timely information.

Mr. Vladeck: HCFA recognizes that the OBRA 93 Data Bank statute not only places a large burden on employers, but may be premature because the information needs under health care reform are not fully developed. We will recommend that Congress enact an 18 month delay in the implementation of the Data Bank. This action will afford us the opportunity to analyze how the Data Bank will work within the context of health care reform and how to more effectively minimize the employer burden.

We look forward to working with you and your colleagues as we review and consider various approaches to improve the effectiveness and the efficiency of our secondary payer programs.

Mr. Bond: What is the status of implementing the OBRA 93 Data Bank? What are HCFA's plans to make the Data Bank workable?

Mr. Vladeck: We recognize that the Data Bank legislation not only places a large burden on employers, but the legislation may be premature because the information needs under health care reform are not fully developed. Therefore, we will recommend that Congress act to provide for an 18 month delay in the implementation of the Data Bank. This action will afford us the opportunity to analyze how the Data Bank will work within the context of health care reform and how to more effectively minimize the employer burden.

However, regardless of the effective date of the Data Bank, HCFA is committed to working with employers to resolve issues surrounding implementation. For example, we plan to publish general preliminary guidance, in the Federal Register, in the very near future. In addition, this past January, HCFA sponsored two meetings for employers at which we discussed Data Bank issues and how they could be resolved.

RISK ADJUSTERS

Senator Bond: Please report to the subcommittee what research, if any, HCFA either has sponsored or plans to sponsor to develop risk adjusters specifically for children, including high risk children with birth defects.

Mr. Vladeck: On January 13, HCFA issued a General Solicitation in the Federal Register to announce the availability of \$3 to \$4 million in funds under cooperative agreements and grants for projects that will focus on major issues in health care reform. Among these projects, risk adjustment was identified as a priority area for study.

The solicitation specifies that risk adjusters need to be designed for both Medicare and non-Medicare populations, including children, to predict expected health care costs based on the health status of the individuals to be covered by a health care system.

Mr. Bond: If HCFA has not sponsored research on risk adjustment for children, would you provide the subcommittee estimates of the federal investment that would be required to bring the development of risk adjusters for children in par with the current state of the art of risk adjustment that has been developed for elderly health plan enrollees.

Mr. Vladeck: It is our expectation that the research that results from the general solicitation, discussed above, will include children and high-risk children in the under-65 risk databases.

Mr. Bond: What are HCFA's plans to invest in development of risk adjustment in response to the President's health care reform proposal which would require federally established risk adjustment methodologies to reflect risk associated with age, sex, health status, and other indicators? Does the administration intend to develop risk adjusters specifically for children?

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Mr. Vladeck: When HCFA evaluates a waiver request, we examine waivers to assure access for all Medicaid patients, including children. Most states apply for waivers for their AFDC population. Because the AFDC population consists mostly of children - a specific risk adjustment for children would be superfluous.

Many children with severe health problems qualify for Medicaid because they meet SSI eligibility criteria. Only Arizona, Rhode Island, two counties in California, and the Philadelphia area have chosen to mandatorily enroll their SSI population in managed care programs.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

MEDICARE/MEDICAID COVERAGE DATA BANK

Mr. Kohl: HCFA requested a supplemental to fund the recently authorized Medicare/Medicaid data bank, which as I understand it would reduce inappropriate Medicare/Medicaid payments by identifying third-party payers. Since the supplemental was not enacted, what else are you doing to enact his money-saving measure as soon as possible?

Mr. Vladeck: In the absence of a Congressional delay in the implementation of the Data Bank, and without additional Fiscal Year 1994 funds to support immediate implementation, HCFA will be forced to re-examine our existing priorities and make hard decisions on which programs and priorities should be funded.

We look forward to working with you and your colleagues as we review and consider various approaches to improve the effectiveness and the efficiency of our secondary payer programs.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until 9:30 a.m., Thursday, March 17, when we will meet in SD-192 to hear testimony from the Director of the NIH and all of the Institute and Center Directors.

[Whereupon, at 12:25 p.m., Wednesday, March 16, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 17.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1995

THURSDAY, MARCH 17, 1994

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:36 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Harkin, Reid, Murray, Hatfield, and Mack.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. HAROLD VARMUS, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ACCOMPANIED BY DENNIS WILLIAMS, DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING REMARKS OF SENATOR HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

Today, the subcommittee will examine the fiscal 1995 budget for the National Institutes of Health. Appearing before our subcommittee will be the Director of the NIH, Dr. Harold Varmus. Dr. Varmus will be followed by a panel of the Directors of all the Institutes and Centers at NIH.

It is, indeed, a pleasure to welcome Dr. Varmus today. This is Dr. Varmus' first formal appearance before our subcommittee. Dr. Varmus comes to the NIH after a distinguished record as a bench scientist, and it is my understanding, Dr. Varmus, that you are the first Nobel Laureate to ever serve as Director of NIH. It is an honor to work with you to ensure both the NIH receives a healthy budget from the subcommittee and that medical research receives the priority it deserves from this administration.

Before beginning your testimony, I will offer some of my views on the President's NIH budget for fiscal 1995 and on medical research in general. First, it appears that the administration has learned some lessons about the importance of NIH to this subcommittee and to the Congress in general. This budget for fiscal

1995 is significantly improved over the one sent to Congress last year.

Despite the pressures of the budget caps and overall squeeze on discretionary spending, for the NIH the President has proposed a \$517 million, or a 4.7-percent increase. This budget increase is funding for all NIH Institutes and Centers. Moreover, the administration now lists the entire NIH as one of its investment priorities, so that is good news.

However, there are some serious fault lines lying beneath the surface of the President's NIH budget for the next year that warrant closer inspection and concern. First, the \$517 million increase for NIH—of the \$517 million increase, the administration has earmarked \$209.8 million for its targeted research for breast cancer, AIDS, minority and womens health, tuberculosis, and high performance computing. Removing these targeted increases reduces the increase for the rest of NIH to just 2.8 percent. That is significantly less than the projected 4.1-percent medical inflation index for the next year.

Of equal concern are the budgetary gimmicks the administration employs to reduce outlays while maintaining NIH's increase in budget authority. Those gimmicks could seriously jeopardize the increases for NIH. Let me go through those.

First, the President's NIH budget requests \$121 million in delayed obligations. That translates into a \$54 million reduction in outlays, reduced for next year.

The administration is also seeking a pause in direct costs, whereby an institution's indirect cost total for fiscal year 1995 shall not exceed its fiscal year 1994 levels. This pause, if approved, could save up to \$80 million in outlays, so these gimmicks produce up to \$134 million in outlay savings, but if they are not accepted by this committee, these budget tricks potentially jeopardize more than \$300 million in NIH's budget authority. That equals more than 60 percent of NIH's proposed increase for next year.

In short, NIH's budget looks good on first glance, but it is built on a shaky foundation, which leads me to saying that what is needed for NIH is a long-term solution and a long-term investment strategy for medical research. I believe that medical research should be a major component of any health care plan passed by Congress. Medical research is a key to eliminating diseases and making the health care system less costly and more effective.

To do this requires a major boost in our investment in medical research, a boost that we cannot find just through the normal appropriation process. That is why Senator Hatfield and I, along with Senator Kennedy and Senator Kassebaum, have introduced the fund for health research as an amendment to the President's health reform package and all other health reform bills offered this year.

We all know what we are talking about—a 1-percent set-aside as well as proceeds from a voluntary check-off from Federal income tax forms to produce between \$5 billion and \$6 billion for additional resources for NIH, or a 50-percent increase in its current budget.

I have been working on this personally for over 3 years. Now, more than 200 prevention, aging, patient, and other health care or-

ganizations have endorsed this proposal, and equally important, most Americans support it also. In a recent Lewis Harris poll, 9 out of 10 Americans favored spending more money on health research, and more than 77 percent said they would be willing to pay more than \$1 more per week in insurance premiums to support health research, so our task now is to attach this to whatever package comes before Congress this year.

So Dr. Varmus, I want to welcome you to the subcommittee. I look forward to working with you and the other Directors over the next year and in the future. I want to assure you that NIH remains very high on our agenda, and we want to all ensure that NIH remains the world's premier medical research institution. At this time, I would yield to my good friend and the distinguished ranking Republican member of the entire Appropriations Committee, Senator Mark Hatfield.

OPENING STATEMENT OF SENATOR MARK O. HATFIELD

Senator HATFIELD. Thank you, Mr. Chairman. I do wish to welcome Dr. Varmus and his distinguished associates. Mr. Chairman, I do not recall having seen a more distinguished group of Americans in one gathering since the dedication of the Reagan Library out at California, when five Presidents of the United States were on the platform, and I mean that, because these people today represent truly the great hope for so many people in our country and the world in what their mission in life represents.

I want also to say to you, Dr. Varmus, and each of the distinguished Directors and associates, that we would not be in the position, even though it is far from our hope and our objective, that we are in today at NIH if it had not been for our chairman.

You know, after 12 years of political draught for the Democrats, they finally won a Presidency, and for a member of that party in the first budget prepared by the new President to analyze it and to critique it the way Senator Harkin did last year, when it represented a reduction in 9 of the 19 Institutes, took a lot of political courage, and he did it with grace, but he did it with very sharp facts that penetrated to the heart of the problem, and it was in his leadership and those of us who believed as he did that we had to address this very serious deficiency in President Clinton's first budget for NIH that led to the 5.2-percent increase over his request level.

I just want to take this occasion, as I have at other times, to comment on the leadership that Senator Harkin has given to not just this committee that he chairs but to the entire cause of medical research and the future hope we have in finding answers to so many of these diseases that beset us, and to recognize that it is indeed a cornerstone of any cost containment that we have to consider within any comprehensive medical program.

As Senator Harkin has said, we have now to attach it to some legislative vehicles. We are not going to be particular. We are not going to be overly sensitive which vehicle it finally ends up on. We are just going to attach it to everything that moves in the Senate.

I just wanted to take this occasion, Senator, to commend you on your excellent leadership, and to be your assistant in any of these things is a great pleasure.

Senator HARKIN. Senator, let me just respond in kind by thanking you for those very kind words, but I happen to be here by happenstance. I can assure you that whatever I have been able to do in terms of supporting medical research, at the NIH in particular, I do by dint of being able to stand on the shoulders of giants, two in particular, Mark Hatfield and Lowell Weicker, who came before me. I learned a lot from both of you, and I again thank you very much for your help, your support, and your leadership in this area long before I ever got here. I appreciate it very much.

I yield now to Senator Murray for any opening statement.

OPENING REMARKS OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you, Mr. Chairman. I do not have an opening statement. I just will let you know that I have to leave for a budget hearing at 10 a.m., but I did want to come here at least initially to let you know of my strong support for funding for research, particularly for women's health research and breast and ovarian cancer. There are a number of us that are going to be watching to make sure that those are well-funded.

I see that Dr. Broder is here. We had a long conversation with him last week about some of the concerns we have about the mixed messages coming out about mammography for women across this Nation. I want to reiterate that, and to let you know that I will be with you as we try to make sure we have all these programs funded.

Senator HARKIN. Thank you very much, Ms. Murray. Godspeed on the budget, and I take what I just said about the gimmicks back.

Senator Mack.

OPENING REMARKS OF SENATOR CONNIE MACK

Senator MACK. Thank you, Senator Harkin. I do not have a prepared opening statement, but I do want to, I guess—maybe this is the beginning of a mutual admiration society, which would not be bad for the Congress.

I want to follow on with the words of Mark Hatfield. Last year was my first year on the committee, and I felt that the approach that you took last year again was one that was extremely helpful, and I think it probably was the reason that we see the kind of additional funding recommended by the administration this year, but I think it really did make a difference.

Each of us on this committee, whether Democrat or Republican, male or female, conservative or liberal, I am sure has many of the same experiences where we have an opportunity to speak with constituents who experience the diseases that you all are engaged in, trying to find both the reason or the cause and a cure.

I cannot think of anything in this Government of ours that is more important than the research and the support, frankly, that we give you. It is more than just the dollars, I think. I think it is the support that this committee has given in the past that is important, as well as the money.

So I look forward to hearing from you all today. There are several areas that I want to pursue, but I will wait and do that in my time.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Mack, and I speak for myself and I am sure for Senator Specter, the ranking member, and certainly Senator Hatfield, in thanking you for being on this subcommittee. We are delighted to have you. You have been a great member. I know of your great interest in medical research. We need more of you in the Senate. I am just glad you are on this subcommittee.

I will leave the record open for any opening statements by Senator Specter.

For the first panel, just for the Senators' knowledge, we ask that the questions be directed only to Dr. Varmus. We will hear from Dr. Varmus first, we will proceed with questioning, and then we will move to a second panel which will have all of the NIH Institute and Center Directors at the table, if that will be satisfactory.

Senator HATFIELD. Mr. Chairman, could you yield for just a second?

Senator HARKIN. Certainly. Certainly.

Senator HATFIELD. I think we might take note today that we have two of our Directors who are leaving. This will be their last appearance before our committee—Dr. Hinshaw and Dr. Loe—and we have two who are here for the first time: Dr. Cowdry and Dr. Leshner.

Senator HARKIN. We will certainly take note of that. Thank you for mentioning that, Senator Hatfield, and again, we certainly appreciate the work that they have done. We will get to that also in the second panel.

Dr. Varmus, welcome to the subcommittee.

SUMMARY STATEMENT OF DR. HAROLD VARMUS

Dr. VARMUS. Thank you, Mr. Chairman.

Senator HARKIN. Please proceed as you so desire.

Dr. VARMUS. It is a pleasure to be here, especially in this rosy glow of bipartisan euphoria that you have created.

INTRODUCTION OF ASSOCIATES

Before I begin with my statement, I would like to introduce my colleagues from the Office of the Director who are arrayed beside me.

On my left, Ruth Kirschstein, Deputy Director. Michael Gottesman is the Acting Deputy Director for Intramural Research. Dr. Wendy Baldwin, who is the newly appointed Deputy Director for Extramural Research.

To my right, Ms. Francine Little, the Acting Director of the Division of Financial Management, Dr. William Paul, whom you have been reading about in the paper, the newly appointed Director of the Office of AIDS Research, Mr. Stephen Ficca, who is the Associate Director for Research Services, Ms. Daryl Chamblee, the Acting Director for Science Policy and Technology Transfer, and down at the end I want to introduce Mr. Dennis Williams, the Deputy As-

sistant Secretary for the Budget in the Department of Health and Human Services, who will be assisting us as we go along.

As you mentioned, Mr. Chairman, this is my first opportunity to appear before you as the Director of the National Institutes of Health, and I am pleased to present the President's budget for the fiscal year 1995.

Given the constraints, which I am sure we will discuss, under which this budget was formulated, I believe it does reflect the commitment of the President and Secretary Shalala to basic science, to technology, to health care, and to investment in the Nation's future.

BASIC RESEARCH

We propose this budget with the recognition that biological sciences are in an era of remarkable productivity, growth, and promise. That promise emerges from a multiplicity of disciplines that offer us remarkable prospects for the future: structural biology, which allows us to envision the three-dimensional structure of proteins and nucleic acids with implications for the design of new drugs; molecular biology, which is allowing us to read our genes and understand the function of all the genes and chromosomes; cell biology and biochemistry, which are allowing us to understand precisely how cells work and molecules respond to signals perceived from outside; the neurosciences, which, in combination with genetics, are teaching us how nerve cells work, how they communicate with each other, and to use that information to understand processes as complicated as cognition and the behavior of individuals.

This is an era of expanding vistas, and the budget I present today has to represent a compromise between the fiscal necessities and the scientific possibilities I will describe.

SCIENTIFIC ADVANCES

In the past year, as in many years in the recent decade, investigators supported by the NIH have reported many important advances. I have chosen three examples that illustrate our ability to improve human health.

First, the isolation of genes involved in causation of colon cancer: in the last several months, first in September and then, conveniently enough, yesterday, two groups of investigators have isolated two genes, one from chromosome two and one from chromosome three, that we know to be implicated in the causation of cancer of the colon.

There are probably 1 million individuals or more in this country who have inherited abnormal copies of either of those two genes. Those individuals will account, on an annual basis, for approximately 15,000 to 20,000 cases of colon cancer each year. Thanks to the isolation of these genes, within the foreseeable future there will be tests that allow for identification of those individuals at risk.

This is not an idle gesture. Those individuals can then be screened by colonoscopy to allow early detection of the cancer and a greater likelihood of cure.

Second, in the area of control of diabetes, two large-scale clinical studies have changed the way in which we manage diabetes in this

country, and have offered remarkable opportunities for curtailing the drastic sequelae of insulin-dependent diabetes. The control of blood sugar through careful monitoring, and the use of a drug known as captopril—a drug initially developed for the treatment of high blood pressure—have been shown to decrease appreciably the consequences of diabetes with respect to the eye and the kidney. This is going to result in longer and healthier lives for diabetic individuals and reduced cost for management of the disease.

Third, it has been shown in the last few months that the use of AZT in pregnant mothers who are infected with HIV, the AIDS virus, can markedly diminish transmission of that virus to infants. This means that if all pregnant women at risk can be identified and properly treated, 1,000 infants who would ordinarily be born with HIV infection will be born free of infection and free of disease.

I emphasize these three areas of discovery because they have obvious and important effects upon human health, and therefore, they thereby fulfill the overarching goal of our agency.

EFFECTS OF LONG-TERM INVESTMENT IN BASIC RESEARCH

But results like this, as I am sure you understand, Mr. Chairman, are the culmination of a process that builds on many less heralded discoveries in previous years. For example, isolation and understanding of the colon cancer genes that I described depend on 30 years of development of technologies to allow the isolation of those genes and over 30 years of study of a class of genes that control the accuracy with which DNA is maintained in our chromosomes.

This vindicates, on the one hand, a remarkable investment in understanding how DNA damage is repaired, and it also allows us to understand a new mechanism by which cancer is caused. Techniques for isolating genes have yielded many other dividends in the past year that I have not had a chance to describe, including the isolation of a gene for Lou Gehrig's disease, for Huntington's disease, and for other inherited cancers.

The development of the drug captopril, which is influential in the control of diabetes, became possible through careful study of an enzyme called ACE about 20 years ago, and through the use of the methods of basic chemistry to design inhibitors of this enzyme. For example, captopril, an inhibitor, controls hypertension, or high blood pressure, but also, we have learned recently, controls the sequelae of diabetes.

The drug AZT, which is now being used to treat HIV infections in pregnant women, was developed initially in the 1960's, before we knew anything about AIDS, and was used as an anticancer drug candidate. Our ability to use that drug in the treatment of HIV depends upon the discovery in 1970 of an enzyme known as reverse transcriptase, the target for the drug AZT. Again, this discovery uses viruses from chickens and mice.

RECENT SCIENTIFIC ADVANCES

This look backward shows that the clinical triumphs that we enjoy this year have been possible only through slow and steady progress in many fields of basic science. The crux of my argument

to you today is because of this relationship. It is important for us to understand the success of NIH in the past year not only by the kinds of clinical triumphs that I have mentioned, but also on the basis of excellence and leadership in basic science that we can demonstrate by a variety of criteria, for such success foreshadows clinical success in the future.

Several fields of research were so remarkably productive in the last year that I want to say a word or two about them before we go on to further questions.

First, in the area of cell biology, there has been in the past year the crowning culmination of our efforts to understand how signals are understood in cells—how a cell receives at its surface a signal from the outside that can be interpreted by the cell as a message to grow, to divide, to differentiate, or to die. There is a network of molecules that recognizes that signal, translates it to the interior of the cell, and allows the cell to undergo the physiological changes that result. We now know the sequence of steps in great detail.

Second, in the area of structural biology, of the many molecules that have been now put forward for us in glorious detail in three-dimensional structures, one of the most remarkable is the molecule known as myosin, the piston in the motor that drives muscular activity and allows the inner components of our cells to move around. The achievement of this longstanding goal of understanding myosin is already yielding remarkable clinical dividends because an important disease, an inherited disease that is not uncommon, called hypertrophic cardiomyopathy. This disease, which fells young athletes fairly frequently, can now be understood and predictions made about the fates of these patients, as a result of our understanding of the three-dimensional structure of myosin.

Third, over the last decade investigators have learned how to manipulate the genes of mice to add or subtract genes from chromosomes. This allows us to create, in mice, animal models for human disease that offer remarkable prospects for understanding the development of the disease, and to engineer new therapies.

The picture I have tried to draw suggests this is a remarkable time to assume the leadership of NIH. On the one hand, biomedical and behavioral scientists are exhilarated by the prospects for understanding biological systems and improving the Nation's health. On the other hand, we are constrained by economic factors known only too well to you that slow down our ability to pursue these goals.

REVISED MANAGEMENT POLICIES

Under the circumstances, it is necessary for me as an executive of an institution like the NIH to convince the public that provides our funds, as well as the scientists who compete for them, that we are doing the best we can to manage the money made available to us.

I would like in the closing moments to list for you some of the initiatives, principles, and developments that allow me to pursue the goals of NIH in a more equitable and efficient fashion.

First, we are paying considerable attention to improving the intramural research program at NIH. You will hear, I am sure, during our questions, about a report of our activities that is in prepa-

ration. If there is a chance, I will tell you about some of the new programs that have been initiated to allow workers in several disciplines to work more effectively together on our campus.

Second, Secretary Shalala and Assistant Secretary Lee have delegated new authorities to me to make personnel decisions. These delegations have been recommended by many committees over many years to improve the efficiency with which I can take decisive action as Director.

REVIEW OF GRANT APPLICATIONS

Third, we are making concerted efforts to improve the way in which we review grant applications in the extramural community. We are using triaging methods that are consistent with the goals of National Performance Review to focus on those applications that are truly competitive. We are also attempting to use computers to improve the efficiency of the grant review process and are taking steps to improve the quality and range of expertise of the study sections that review applications.

NIH OMBUDSMAN FOR EXTRAMURAL COMMUNITY

Fourth, I am concerned about maintaining open communication with the extramural community which receives over 85 percent of our funds. To that end, I have recruited an outstanding extramural scientist, Dr. Howard Schachman of the University of California at Berkeley to serve as an ombudsman for that community.

Dr. Schachman has already been traveling to institutions at which we have major investments, meeting with a wide range of students, faculty, and deans, to report back to me about the community.

ETHICAL AND LEGAL ISSUES IN SCIENTIFIC POLICY

Fifth, we have been confronting major policy issues that range from ethical to legal issues. We have developed panels to look at the implications of work with human embryos. We have been asking about the principles that should guide cosponsorship of research by Government and industry. We have also been looking at guidelines that govern conflicts of interest, and we have made a decision not to pursue patent protection for our previous claims on human CDNA sequences.

I have been concerned, as you know from my confirmation hearing, with enriching and diversifying the culture of science, and we have made a number of efforts to improve the representation of women, minorities, and people with disabilities in our programs.

LOAN REPAYMENT PROGRAM

We are developing a loan repayment program to attract minority candidates to our clinical training programs at NIH. We are centralizing our educational efforts in a single office, and we are developing a comprehensive program in collaboration with Clifford Alexander & Associates to establish a more equitable work place at NIH.

Finally, to do all of these things we need a leadership team, and in the course of the last few months I have had the good fortune to recruit many of the people you see around me today to join me in this effort to maintain the NIH as a vital organization. I am very proud of these people.

PREPARED STATEMENT

We have a number of other searches underway for four Institute Directors and for the newly formed Office of Behavioral and Social Science Research. It is my hope that these initiatives will help us embrace the magnificent new prospects for pursuing our traditional mandate—science in the service of human health. I would be pleased to answer any questions you might have.

[The statement follows:]

STATEMENT OF DR. HAROLD VARMUS

Mr. Chairman, committee members, I am pleased to appear before you for the first time as the Director of the National Institutes of Health to present the President's NIH budget for fiscal year 1995. The President proposes to increase the NIH budget by \$517 million above the current level, to \$11.473 billion. This represents a 4.7 percent increment, slightly above the rate of inflation for biomedical research and substantially above the average ceiling imposed on discretionary spending by the Budget Reconciliation Act of 1993. Given the constraints under which this budget was formulated, I believe it reflects the commitment of President Clinton and Secretary Shalala to basic science, to technology, to health care, and to investment in the Nation's future. The request for the coming year attempts to counter several specific threats to the health of the American people; to promote new initiatives that are likely to have wide benefits; and to sustain the vitality of fundamental research in biology, chemistry, behavioral science, and other fields. There are itemized increases for the study of AIDS, breast cancer, and tuberculosis; we will spend more on neglected aspects of the health of women and minority populations; additional allocations will be made for the application of high performance computing to science and medicine; and substantial increases (over \$300 million) will be devoted to the vast array of scientific activities that NIH traditionally supports. We propose this budget with the recognition that the biological sciences are in a remarkable phase of growth, productivity, and promise. New methods based on physics, chemistry, and computer science are providing detailed visual images of the molecules that govern the behavior of cells, and these methods will usher in a new era in the development of drugs. Molecular biology has opened the window on our genetic endowment, and we are learning the composition and actions of genes that predispose us to disease when we inherit them in abnormal form. Biochemistry is teaching us how our cells respond to the environmental cues that govern growth and differentiation, providing new strategies for the diagnosis and treatment of cancer and other diseases. Neuroscience has revolutionized approaches to the normal brain, its individual cells, and the chemical signals that flow between them; to disorders of the nervous system; and to cognition and behavior. This is an era of expanding vistas, and the budget I am presenting today represents a compromise between fiscal necessities and scientific possibilities.

During the past year investigators supported by the NIH have reported many important achievements that illustrate the potential of NIH to improve the Nation's health. A few examples suffice to display the significance of these advances.

(I) A gene that strongly influences the probability of developing a common form of colon cancer, diagnosed in over 10,000 Americans each year, has been isolated from human chromosome two. Approximately one million people in the U.S. have inherited an abnormal form of this gene and are thus at high risk of contracting the disease. It will soon be possible to identify these people by genetic screening methods; this will allow early detection of disease by colonoscopy and result in the saving of many lives.

(II) Two large-scale clinical studies have changed the standard for optimal management of diabetes. One has established unequivocally the value of precise control of blood sugar for preventing the major complications of insulin-dependent diabetes mellitus—blindness and kidney failure. The other has shown that the drug captopril can protect the kidneys of diabetic patients from progressive disease. In response

to these findings, many of our nation's diabetics will have longer and healthier lives, and costs for management of complications will fall.

(III) The administration of AZT to HIV-infected women during the latter two thirds of pregnancy and to their new born infants has cut the rate of transmission of the virus by 75 percent, without apparent ill effects. Wide application of this method could save over 1,000 American children each year, and many others worldwide, from HIV-induced disease.

I emphasize these findings because they have obvious and important effects on human health, and thereby fulfill the overarching goal of our agency. But results of this sort, with their dramatic effects on prevention and treatment of disease, are the culmination of a process that builds on many, less-heralded discoveries in previous years—discoveries made possible by our Nation's traditional commitment to a long-term investment in biomedical science.

Isolation of the colon cancer gene, for example, depended on over thirty years of developing techniques to localize genes on human chromosomes and to amplify them in bacteria. These techniques are, of course, being used to study many other genetic diseases, largely through the Human Genome Project. In just the past year, NIH-supported investigators have identified the genes for Lou Gehrig's Disease, Huntington's Disease, and inherited cancers other than colon cancer.

The function of the colon cancer gene was rapidly understood because the gene is closely related to bacterial and yeast genes that protect the integrity of DNA by repairing mutations in these other, much simpler organisms. In this way, over twenty years of support for basic studies of DNA damage and repair unexpectedly revealed a new and important mechanism for causing cancer, a mechanism that is likely to have a role in cancers arising in many other organs.

Development of captopril, the drug that benefits diabetic patients, became possible through the careful study of an enzyme, called ACE, that cleaves other proteins. One action of ACE is to convert a small protein to a smaller fragment that regulates blood pressure. Fundamental principles of chemistry were used in the 1970's and 1980's to design ACE inhibitors, such as captopril, that control hypertension, another disease that damages the kidney. The new role for the drug in diabetes is likely to be equally important.

The prevention of maternal transmission of HIV required at least two important events that preceded by many years any knowledge of AIDS or HIV:

(I) the chemical synthesis of AZT, which was originally tested as an anti-cancer drug in the 1960's, and (II) the discovery in 1970 that retroviruses from chickens and mice contain an essential enzyme, reverse transcriptase, with unusual properties, including susceptibility to inhibition by AZT.

This look backwards shows that the clinical triumphs that we enjoy this year have been possible only as a result of steady successes in many fields of basic science—especially bacteriology, virology, enzymology, chemistry, and molecular biology. Because of this relationship between fundamental discoveries in biology and later benefits to health, it is important to gauge the success of NIH in the past fiscal year not simply by the most recent clinical breakthroughs, but also by the standards of scientific productivity and excellence. By many commonly used criteria—publications, citations in the scientific literature, invited presentations at international meetings, prizes, patents, and applications for research training—the United States continues to lead the way in virtually all fields of biomedical research. Several areas of research were so extraordinarily productive in the past year that they need to be singled out, if only to anticipate the beneficial effects we can expect to flow from them in coming years.

(I) Through a combination of genetic and biochemical methods—often using simple experimental organisms, such as yeast, fruit flies, and worms, as well as cells in culture—investigators have learned how signals are transmitted through a cell to direct growth, division, differentiation, and even death. These signaling processes often begin at the surface of the cell and conclude in the nucleus, where genes are controlled. A profound understanding of cellular networks of communication heralds a revolution in the design of therapies for diseases that affect fundamental cell processes, such as cancer and developmental disorders.

(II) The burgeoning field of structural biology continues to provide us with extraordinary images of the three dimensional organization of proteins and nucleic acids. Among the most thrilling of this year's images was the picture of the major working unit of myosin, the piston in the cellular motor that allows muscles to work and subcellular elements to move. The achievement of this long-standing goal promises new approaches to the control of muscle diseases. For example, an inherited disease of heart muscle, responsible for many of the deaths of young athletes, has been traced to single changes at critical positions in myosin motors.

(III) Recently developed techniques to alter genes in the mouse germ line have been used to create mice carrying mutations responsible for many human diseases. These genetically-altered mice provide accessible models for cystic fibrosis, certain cancers, and metabolic and immunological diseases, such as diabetes and lupus. The new prospects for understanding how disease arises and for testing novel therapies are truly remarkable.

The picture I have drawn suggests that this is an especially challenging time to assume the leadership of the NIH. Biomedical and behavioral scientists are exhilarated by the unprecedented opportunities to understand biological systems and advance the healing arts, but we also feel constrained by the economic factors that slow our pursuit of those opportunities. Under such circumstances, it is important to convince the public that provides our funds, as well as those scientists who compete to use them, that the NIH is making the best use of the money available.

Many of my efforts since assuming the directorship in late November have been directed to the goal of making the NIH more efficient and fair. These efforts have been directed at both our intramural and extramural programs, and they concern personnel, peer review, management, and policy.

(I) *Improving the intramural research program.*—As directed by the Appropriations subcommittee last year, I have conducted a careful review of the procedures that govern the intramural research program. A distinguished subcommittee of the Advisory Committee to the Director has made numerous recommendations about our recruitment, evaluation, and promotion of NIH scientists; our training programs; our procedures for budget allocation and program planning; and our facilities, particularly the Clinical Center Complex. I welcome these recommendations and expect to put most of them into effect in the near future. (I will, of course, make the formal report of the subcommittee available to the Congress when it is completed.) In the meantime, with my encouragement, the intramural program has already been strengthened by the formation of inter-Institute groups that focus on cell biology, genetics, structural biology, neuroscience, and immunology, as originally recommended by a committee of intramural scientists in 1992.

(II) *Installing new leadership.*—I have had the good fortune to attract outstanding people to important positions in my new Administration. Among these are Dr. Ruth Kirschstein, the Deputy Director of NIH; Dr. Wendy Baldwin, the Deputy Director for Extramural Research; Dr. William Paul, the Director of the redesigned Office of AIDS Research; Dr. John Gallin, the Director of the Clinical Center; and Dr. Alan Leshner, the Director of the NIDA. Searches are underway for a permanent Deputy Director for Intramural Research and Directors of four other Institutes (NINDS, NIDR, NIMH, and NINR) and of the newly formed Office of Behavioral and Social Sciences.

(III) *Acquiring new authorities.*—In accord with recommendations that have been repeatedly made by committees evaluating the Office of the Director, NIH, many important authorities for promotions, appointments, and other matters have been delegated to me by the Secretary, HHS, and the Assistant Secretary for Health, HHS. These new authorities will increase my ability to take decisive and timely action on many issues.

(IV) *Upgrading peer review.*—Several initiatives are underway to improve the procedures for review of grant applications at NIH. The most significant of these is the use of triaging methods to allow study sections to focus upon those applications that are truly competitive. Committees composed of NIH and extramural personnel are also examining the prospects for using computers to aid in the review of applications and looking for ways to improve the quality and range of expertise of study section members.

(V) *Communicating with extramural scientists.*—To insure that the views of the extramural community are well represented in the formulation of NIH policy, I have recruited an outstanding senior scientist, Dr. Howard Schachman of UC Berkeley, to serve as an ombudsman for that community. Dr. Schachman travels frequently to major biomedical research institutions to listen to students, fellows, faculty at all levels, and administrators about their views on topics ranging from underfunded areas of research to peer review and scientific integrity.

(VI) *Formulating policy.*—The successes of biomedical science have required its leaders to confront new ethical and legal issues. I have devoted considerable attention to these questions in the past few months. The NIH has assembled panels to discuss human embryo research and the co-sponsorship of research by government and industry; we have decided that it is not in the best interest of technology development to appeal a rejection of NIH patent claims on human cDNA sequences; and we are assembling guidelines to advise grantee institutions on conflicts of interest.

(VII) *Enriching and diversifying the culture of science.*—As I indicated at my confirmation hearings before the Senate Committee on Labor and Human Relations, I

believe that the future health of our enterprise requires full development of the scientific talents of our entire society—including women, members of under-represented minority groups, and those with disabilities. This will require closer attention to education and training at all levels. To these ends, we are creating new incentives, including loan repayment, to attract minority candidates to our training programs; centralizing our public and pre-college educational efforts in a single office; and developing a comprehensive program, with the assistance of Clifford Alexander and Associates, to assure a fair and equitable workplace for all NIH employees.

It is my hope that these initiatives will help the NIH to embrace the magnificent new prospects for pursuing our traditional mandate—science in the service of human health.

Thank you Mr. Chairman. I will be pleased to answer any questions you may have.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Senator HARKIN. Dr. Varmus, thank you very much for a very strong statement.

I agree with you, you could not be at NIH in a more exciting time, and I think it is going to get even more exciting in the next few years. Some of the new breakthroughs that are coming I think are just incredible, almost beyond belief, what is happening out there, so you are there at a very, very exciting time.

Of course, we hope with this subcommittee and with our counterparts on the House side, that we can assure that NIH continues its preeminence in the world, and even increases the gap between NIH and everybody else around the world.

I have just a few questions and I will have some more for the record that I will submit in writing, but a couple that I wanted to cover with you now. One deals with some legislation that we had passed previously in 1986.

We had legislation to facilitate the transfer of technology, the Bayh-Dole Act. It set the stage for industry to establish the cooperative research and development agreements, CRADA's.

It is my understanding that recent discussions regarding Government-established price controls and pricing clauses within CRADA's have hampered growth of technology transfer. I understand that CRADA's with the NIH have declined by 83 percent since 1988.

Could you just discuss with us why this may be happening? Do you have a team looking at it? Do you have some examples why this is happening? Is there more than one reason?

Dr. VARMUS. Senator, if I may, I would like to correct the numbers on the decline of CRADA's. There has been some fluctuation between 30 and 58, but the numbers have not really varied in what I would call a statistically significant fashion over the last several years.

Senator HARKIN. Are you saying that since we first started—

Dr. VARMUS. I think I brought with me—

Senator HARKIN [continuing]. The decline of CRADA's have not gone down significantly in the last few years?

Dr. VARMUS. That is correct.

Senator HARKIN. So it has stayed about the same?

Dr. VARMUS. That is correct. The number of CRADA's initiated was 8 in 1986, 38 in 1989, 33 in 1990, and 26, 30, 45 respectively in subsequent years, so the numbers have fluctuated somewhat.

but I think that is only a random fluctuation. We are in the process of developing a data base in conjunction with the Institutes. Should the numbers change significantly, I will notify the committee.

Senator HARKIN. Was 1988 just a high—what was the number for 1988?

Dr. VARMUS. There were 20 CRADA's in 1988, actually. It was on the low side.

Senator HARKIN. Actually, it came up after that.

Dr. VARMUS. Yes; but I am not sure these numbers are very significant, frankly. I think that the number is about the same, but your question does address an issue of concern.

I would like to address it, because it is an important one to us. We have been hearing over the last several months that our own scientists and a number of representatives of industry concerned that exclusive licenses under CRADA agreements will be subject to fair pricing agreements. I think the interpretation of that statement is in the mind of the beholder. Very few of our CRADA's lead to drugs that would, in fact, fall under such controls.

I am concerned that industrial representatives have exaggerated whatever inhibition might be placed upon them as a result of this statement. To try to clear the air on this question, Ms. Chamblee and I are organizing a meeting which will be held in the next month or two, to allow intramural scientists, representatives of industry, and other governmental officials to sit down and talk about the agreement and see if we cannot clear the air.

REGULATION OF RESEARCH AGREEMENTS

We had a rather similar panel discussion 2 months ago to talk about our regulation of so-called sponsored research agreements, agreements in which extramural institutions combine with industry to fund research at our grantee institutions. A number of concerns had been raised in that arena as a result of our insistence that some changes be made in an agreement that had been struck between Sandoz Pharmaceutical and the Scripps Institute.

We wanted to air those issues and describe, for the potential investors and for the institutions, how we might better manage sponsored research agreements. I think we have achieved a great deal there by developing some guidelines and winning back some trust, so I am hoping that we will be able to do the same thing in our discussion of CRADA obligations next month.

Senator HARKIN. I am glad you cleared that up. I would like to see some more of those figures. Not now, but I will get those from you.

Dr. VARMUS. We will get those to you for the record.

[The information follows:]

National Institutes of Health—Executed CRADA's fiscal year 1986-93

Fiscal year:	Number
1986	8
1987	12
1988	20
1989	38
1990	33
1991	26
1992	30
1993	45

INTRAMURAL PROGRAM REVIEW

Senator HARKIN. And we will continue our discussions on that.

You mentioned in your remarks the intramural program and the report that we had requested in fiscal year 1994 on the intramural program. I guess the task force is wrapping up its report. Can we have one? When can we expect to see something?

Dr. VARMUS. The task force has met five or six times. They have prepared a draft. A summary statement could be available for a look in its draft form. I caution you that the draft form has not been reviewed by my staff or by departmental officials, but we would be happy to share it with you.

Senator HARKIN. So no preliminary conclusions yet?

Dr. VARMUS. It addresses a number of concerns about maintaining the vitality of the intramural program through recruitment and training and evaluation processes. It addresses the way in which the Institutes divide their resources between the intramural and extramural program, and it also talks about the need for refurbishment of the clinical center and has some suggestions about how the clinical center would be restructured over the next several years.

Senator HARKIN. I was going to ask you about that. So there are suggestions in there?

Dr. VARMUS. Yes; there are.

CLINICAL CENTER INFRASTRUCTURE

Senator HARKIN. Is there anything more you can tell us about the clinical center at all?

Dr. VARMUS. Well, I would be happy to share the conclusion that the committee does feel that the clinical center performs functions essential to the activity of the intramural program; that although the building is in a state of increasing decay, it should be rejuvenated; and that they endorse strongly the purpose of the clinical center structure. There are, of course, some suggestions about the size and what kind of activity should go on there, that I think we could talk about later on.

Senator HARKIN. Did Mrs. Clinton get a look at the clinical center?

Dr. VARMUS. Yes; she did. When Mrs. Clinton came to NIH, we did not want to spend too much time moving her around, so we focused all her activities in the clinical center. We had tutorials in a conference room where she heard about science that was going on in genetics and immunology and neurobiology and other disciplines. We had an opportunity to show her patients who were undergoing clinical trials for AIDS and gene therapy protocols. The patients were in wards adjacent to laboratory space, emphasizing the importance of having laboratory space and clinical space side by side for some of our clinical programs.

Senator HARKIN. Great. I appreciate it.

Senator Hatfield.

EFFECT OF FTE REDUCTIONS ON NIH

Senator HATFIELD. Thank you, Mr. Chairman. Dr. Varmus, would you share with the committee today the point we were discussing last week about the administration's requirement to reduce

your senior positions to meet FTE requirement levels, and the relationship of those senior positions to senior scientists rather than just administrators?

As you know, Mr. Chairman, the administration has sought to reduce the number of employees in the Federal Government. Some of these across-the-board reductions in categories do not necessarily fit the NIH precisely the same way as it might over in the Veterans Department or the Energy Department.

Could you tell us if you are getting some kind of flexibility to that regulation or to that order?

Dr. VARMUS. Well, I welcome that question, Senator. As you know, the President has asked that the Government be reduced by 252,000, and that includes several thousand at NIH. So far we have reduced our staff by about 500 in the intramural program and about 200 in the research management services over the course of the last 3 years.

Because the intramural research program is dealt with as an administrative activity, we are reducing that program as though it were administrative activity when, of course, it is a scientific, academic activity. Reductions both in the intramural program and in research management support result in the loss not only of individuals, but of programs, because each of these individuals is involved in managing either intramural or extramural research programs.

Then as you point out, we have had a special target for reductions in the upper level, GS-14 and above level, 10 percent of the total reduction. Now, in Government, across the board, these positions are often filled by middle-level managers who are transferring directions downstream. At NIH, most of our senior-level people at GS-14, GS-15, and SES positions, are, in fact, managing research groups with a small number of postdoctoral fellows and students. And each reduction, of course, has an impact on our ability to pursue the kinds of research objectives that I mentioned.

RECRUITMENT AND RETENTION OF SENIOR SCIENTISTS

We are achieving reductions in these categories, but it is difficult. There are very poor inducements to retirement. The very fact that we have such reductions in progress makes it difficult for us to recruit and retain outstanding individuals. We are negotiating with the Department to obtain some remission of these administrative strictures to take into consideration at least one-half of our high-level individuals are working scientists and not in administrative categories.

Another important flexibility is the delegation of authority to make appointments in the so-called senior biomedical research service series, and we are negotiating at the moment with the Department in efforts to obtain such delegations.

Senator HATFIELD. You might turn some of them into consultants.

Dr. VARMUS. There are a number of ways.

Senator HATFIELD. I hope that they are responsive at OMB and the agencies enforcing this, because I think it would be disastrous for us to try to be increasing dollars for research and at the same time you are having to reduce those personnel who are in positions to implement that research. If you have difficulty, I would like to

know, because I am sure Senator Harkin and I can add our voice to plead for reason in the application of this.

Dr. VARMUS. Thank you. We appreciate your help.

HEARING AID CLINICAL TRIAL

Senator HATFIELD. I told the chairman—I am going to have to go to another session, but I would like to ask Dr. Snow before I leave, if I could, how the hearing aid project is coming? You might guess I have a special interest in that. By the way, I have a marvelous advance in that technology, which is still pretty primitive. I can elevate my volume and I have two modes; I have one for all of you and I have one for my wife. [Laughter.]

So selective hearing.

Senator MACK. Is there any way for us to know when you have tuned us out? [Laughter.]

Senator HATFIELD. As you know, this project started in the Veterans Administration and I was just interested in knowing how it is progressing. Also, could you indicate to us what the division is between your grants to basic research and to clinical research? And I would like to also have you define what you call clinical research.

Dr. SNOW. Senator Hatfield, the collaboration with the Department of Veterans Affairs on hearing aid research and development is coming along very well. As I think you know, the first thing we did was to survey the field and see where the situation was in hearing aid research; and we accomplished that in 1992, finishing it in 1993.

We have now issued one program announcement, and I think that is a good example of the basic research that will be supported by this initiative. This is a program announcement on the understanding of speech with a hearing aid, both in quiet and in noise. A more applied program announcement that is shortly to be published has to do with the evaluation endpoints of amplification benefit for individuals who are hearing impaired.

A very important part of the collaboration is the program of device development which we plan to do through a contract, and we hope to publish the request for proposals within the next few weeks. This will allow us to examine existing, as well as newly developed strategies and technologies and it will also lead to device development. This will be laboratory work that can then be applied in the field.

The field testing of both existing and newly developed strategies in hearing aid technology will be carried out in clinical trials. These clinical trials will be carried out in VA medical centers with recruitment of additional women from either nearby universities or community speech and hearing centers, or from other sources.

The principal problem with hearing aids is the inability to understand speech in background noise, as you well know, and these clinical trials addresses that problem. We believe that there are subgroups of individuals with hearing impairment who may benefit from certain strategies and not from others. The purpose of these clinical trials is to identify which subgroups of hearing-impaired persons benefit from which technologies and under what circumstances.

In the past, clinical trials for hearing aids have taken place in the marketplace. If a strategy sold well, it stayed; if it did not, it was dropped. We believe that there are many strategies that do benefit subgroups of the hearing-impaired population that we can identify.

We envision a series of clinical trials. The protocol is almost complete for the first clinical trial. The protocol-writing committee began in September 1993, has just met in February, and will finalize the protocol during April. We hope to start the clinical trial in September 1994.

This clinical trial examines the most fundamental questions; which individuals and under what circumstances is linear amplification superior to wide dynamic range compression amplification? A superb protocol has been written. It is of the highest scientific quality and I think will give us the answers to these questions.

Then a series of questions will fall into line that can be answered by clinical trials. We envision a clinical trial beginning every year or two, and this process may extend, if the job is well done, over the next 15 to 20 years, to answer many important questions. We are also going to sponsor a scientific forum so that the results of hearing aid research and development can be presented. This conference will stimulate activity within the scientific community.

Senator HATFIELD. Thank you, Dr. Snow. I have some follow-up questions I would like to present to you and to you, Dr. Varmus.

Thank you, Mr. Chairman.

Senator HARKIN. Senator Reid.

SUCCESS RATES IN AWARDING GRANTS

Senator REID. Thank you, Mr. Chairman. Would you, Dr. Varmus, have each of the directors of the Institutes supply to the committee and to me personally the percentage of grants that are given in comparison to those that are requested? Do you understand the question?

Dr. VARMUS. Yes; the numbers are readily available, Senator.

Senator REID. My concern is if we arrive at a point where there are so few given, less people will try and I think overall we achieve less. Would you agree?

Dr. VARMUS. Yes; I would.

Senator REID. Are we at a point where that is a concern?

Dr. VARMUS. Yes; the success rate, depending on the Institute and depending on the nature of the program, varies from 10 to 40 or 50 percent. But on average the success rate in recent years has hovered around 24, 25, 27 percent. In my own view and experience as an investigator and grant reviewer, it is very difficult to make distinctions among grants when one is looking at the top one-third of the grants. And it would be, to my mind, helpful to the health of our enterprise if we were able to fund approximately one-third of the grant applications that we receive.

LOAN REPAYMENT

Senator REID. One of my visits to the National Institutes, I was told that there was a program that had been instituted to allow sci-

entists who were interested in studying the problems related to AIDS to have part of their student loans forgiven.

Dr. VARMUS. That is correct.

Senator REID. I offered legislation, that is part of the NIH bill that was vetoed and then we finally passed it, that broadened that. Are you aware of that?

Dr. VARMUS. Yes.

Senator REID. Have you had a chance to do anything with that yet?

Dr. VARMUS. We are attempting to broaden this to encourage minority scientists, particularly minority physicians, to come to NIH for training programs. Dr. Gottesman and I have been working with our staff to try to generate as early as this coming year a set of fellowships that will be sponsored in part by my own discretionary fund to allow debt forgiveness, as an inducement to encouraging minority physicians to become clinical scientists.

Senator REID. In addition to the minorities, it is my understanding that generally some of the better scientists are unable to come because they owe so much money and simply have to go out and try to repay those loans.

Dr. VARMUS. Yes.

Senator REID. So I guess your problem is finding money. You now have the authority to do that, you just do not have the money to do it, is that correct?

Dr. VARMUS. We are currently spending \$1 million in loan-forgiveness programs at NIH.

Senator REID. Is that a line item or is that just something that you have at your discretion?

Dr. VARMUS. It is included in the budget of the Office of the Director.

Senator REID. But is there a line item for that purpose?

Dr. VARMUS. Yes; there is.

Senator REID. Mr. Chairman, I think that is something that we should take a real close look at, to see if we can expand that a little bit. I think we should try to get as many of the best and the brightest to come to the National Institutes and not be prohibited because they simply cannot afford to come.

I have a couple of questions, Mr. Chairman, of Dr. Gordon.

Dr. Gordon, you have been instrumental in effecting many positive—

Senator HARKIN. I am sorry. You came a little late, Senator.

Senator REID. He is not here?

Senator HARKIN. No; we tried to keep the first panel just for the Director and as soon as we finished the questioning for Dr. Varmus—

Senator REID. Then we go to the individuals?

Senator HARKIN. We will have the rest of the Directors come up and take their places at the table.

Senator REID. What I am going to do, Mr. Chairman, is I have some questions.

Senator HARKIN. Senator Hatfield just had to leave.

Senator REID. I understand rank does have its preference.
[Laughter.]

And I appreciate that. What I will do if I am not able to remain here, I will submit these questions to the individual institutes. I have questions of two specific ones.

UNDER-REPRESENTATION OF SUBGROUPS IN RESEARCH STUDIES

Dr. Varmus, as you know, women, we have found, are not often represented or are under-represented in biomedical research studies. That has certainly been the case in the past. For this reason, I joined with a number of others as an original supporter of the establishment of the Office of Women's Health within NIH. What achievements has the Office of Research on Women's Health made in attempting to rectify this inequity?

Dr. VARMUS. Well, one of the most important things that has just happened, Senator, is the publication of our inclusion guidelines for minorities and women. This is the result of directions in our Revitalization Act, and it alerts all clinical investigators that every clinical project that is submitted for approval to the NIH must show evidence that consideration has been given to the inclusion of women and minority groups, including subgroups, in the design of clinical studies.

Now we are attempting to advise the clinical community, as it attempts to understand these guidelines, about the nature of the subgroups. It has been our policy for some time to ensure that women are being included in studies. We now have clearly written guidelines that allow us to help investigators in formulating their grant applications.

DISEASES AFFECTING WOMEN

Senator REID. I appreciate that. I wish we would be more aggressive, though, in going after diseases that affect women specifically, like interstitial cystitis, lupus, and all these other things.

Dr. VARMUS. As you know, we do have programs which you will probably hear about later in the hearing, that address some of these specific conditions. We also have a major initiative in this year's budget for research on breast cancer, and we have many programs within the Institutes addressing ovarian cancer and other diseases that are specific to women.

In addition, as I am sure you are aware, the NIH has mounted, even before I came on board, the women's health initiative, which addresses many of the major concerns of postmenopausal women: Osteoporosis, breast cancer, and other diseases.

Senator REID. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Reid. Thank you for your understanding.

Senator Mack.

Senator MACK. Thank you, Mr. Chairman.

It had been my intention to stay for the full hearing, because I have a series of questions that I would like to pose. But I may have to go to the floor, since there is an amendment that is being offered by Senator Kerry having to do with flood insurance that is going to have a significant impact on my State. And I feel the need that I vote.

Senator HARKIN. We had the floods. [Laughter.]

EARMARKING

Senator MACK. I think you had the most recent. And if there are a few more you would like to have, I would be delighted to head them your way.

But I want to take this opportunity, anyway, to raise a couple of questions. And it might be appropriate, after this last discussion, to raise the question of earmarks. The President's proposal emphasizes funding for breast cancer research. And obviously I am very sensitive to this. My wife is a breast cancer survivor. My mother is a breast cancer survivor. But, yet, if one looks at the incidence, the mortality and funding levels of breast cancer versus prostate cancer, for example, or other forms of cancer which are prominent in women, the numbers appear skewed.

Last year, NIH's appropriation was the first in many years which did not earmark specific research projects. How do you view the issue of earmarking of biomedical research funding? Should not these decisions be left to the research community?

Now, having said that, I also hear from others that there are biases within the research community; that there are individuals that will pursue something for whatever reason, and obviously, then, it is very legitimate for representatives of the people to raise questions about, in fact, how we are doing this. And then, there is a tendency in the political realm for representatives to try to use their influence to direct where we should be investing our dollars. It is a very difficult question.

I must say to you that my approach, at least to date, has been one of saying, who am I to try to say to you and other members of NIH where you ought to be spending this money? I would like to hear from you. I would like for you to be telling us where we ought to be investing this money, so that we get the best research for it.

So, if you would be kind enough to address that issue.

Dr. VARMUS. Yes; let me say a few words about this issue of so-called earmarking. I prefer to call it targeting or investment spending. In an ideal world, from the NIH point of view, we would not only spend the money as we saw fit, but everyone would understand we were spending the money in the best possible way.

I see the current process of identifying investment areas as a way of advertising to the public and to Congress that we have a deliberative process with the Congress and with the administration. Because these are not designations that are simply being placed upon us. We do negotiate with the Department and with the White House and with others about how these investment areas are defined.

I think what we are trying to show the public is that we do have, behind NIH's somewhat vague mission to improve health, specific goals that we would like to pursue: the conquest of AIDS, progress against breast cancer, development of certain specific technologies that relate to the use of computers in research, progress against a new threat from tuberculosis.

These are identified targets that we would be pursuing in most cases anyway, but we state them explicitly so the public can understand some of the specific goals of our mission.

Senator MACK. Let me just toss in another thought here.
Dr. VARMUS. Yes.

INFLUENCE OF INTEREST GROUPS ON RESEARCH

Senator MACK. Is there not a risk, however, of sending a message, depending on your responsiveness to certain interest groups, that the way to influence research in the country is by the development of massive grassroots political activism in order to pressure you to move one way or another?

Dr. VARMUS. I think the NIH has reason to welcome interest by concerned parties—for example, those who have these diseases—in what we do. They have viewpoints that are worth hearing. I think it gives a sense of strength to those groups to know that we do listen to their complaints.

I do not think we should accept their dicta at face value because we must view them in the context of politics, economics, scientific possibility, and our own view of where we should be proceeding. But having these views brought forward is not something that I resist.

Senator MACK. Sure.

DISEASE-SPECIFIC RESEARCH AND ITS BROAD-BASED EFFECTS

Dr. VARMUS. I would make one other point, and that is that when we talk about breast cancer as an initiative—and this is an area I am very familiar with, because my own research is largely in this area—we are not simply talking about working with breast cancers from human beings. We are talking about developing a large research portfolio that has an impact upon our understanding of cell biology, how cells become cancer cells. It is a very broad initiative in which we are trying to understand genetics, environmental influences, and psychosocial problems that affect breast cancer.

Many of the sciences that I mentioned earlier—nerve biology and structural biology and cell biology—all have their impact on this problem. What we are trying to do in the context of the designated increase for breast cancer research, which brings our total support of breast cancer to \$384 million this year, is to show the multiplicity of forces that we can bring to bear on this problem.

At the same time, work that begins as breast cancer in a fairly narrow sense often has dividends, as it did in my own work for the study of the nervous system. Conversely, we know that work in cell biology and genetics that may not seem breast cancer-specific initially has valuable dividends for an understanding of breast cancer.

In some ways, the so-called investment strategy, or earmarking as you call it, gives us an opportunity to explain to the public that work that may not seem immediately obvious as breast cancer related is in fact deeply significant for those who are suffering from this disease.

REVIEW OF PEER REVIEW PROCESS FOR CLINICAL RESEARCH

Senator MACK. I will let it go at that, again, because of my time limitation here.

You indicated during your confirmation hearing that you intended to examine the peer review process for grant applications. You have also commented on the need to bring scientific advances from the bench to the bedside. In May 1993, the National Cancer Advisory Board concluded that the current peer review system is contributing to, "a crisis in clinical research, and recommended the creation of a specific study section to review project grant applications for clinical cancer research."

And, recently, Senator Inouye and I, along with 10 of our colleagues, sent you a letter suggesting the need for a specific study section for the review of clinical cancer research project grant applications. As you know, we are not proposing that clinical cancer research proposals be automatically funded or that they be given preferential treatment—only that they be reviewed by clinical research evaluators.

Now, I am interested in what action, if any, has been taken on this issue.

Dr. VARMUS. Of course, Senator, as you know, if the study section is created, per force, there will be grants in that area. So, there is a kind of entitlement that is built into the creation of a study section that is specifically designated to address one fairly narrowly defined problem.

I would point out a number of things about your suggestion. First, only about one-third of our clinical research is funded as a result of review by our traditional Division of Research Grants-type of study section. Two-thirds of our clinical research is funded through special panels that are developed within the Institutes. So, within the Cancer Institute, for example, there are a number of special panels that are reviewing only, or largely, clinical research.

Now, there is a problem in defining what clinical research actually is, but the conventional wisdom is that it requires having a patient and a doctor in the same room at the same time, and both of them are alive. [Laughter.]

Given that definition, there are a number of panels already existing within the Institutes that are reviewing special program grants. For example, in cancer research, the Specialized Programs of Research Excellence [SPORE'S] Program, is specifically designated to bring basic research to the bedside and to initiate programs that involve therapeutic trials.

Now, we do have a large number of clinical applications, roughly one-third, that are reviewed in our conventional study section system. And I have read letters of complaint from many in the clinical research community that their applications tend to be less well received than grants from basic researchers.

I feel clinical research is an important part of our research portfolio. As a consequence of these letters and my interest in seeing excellent clinical research done, I have asked Jerry Green, the director of the Division of Research Grants, to look carefully at the way in which review is accorded to those applications. He has begun that investigation process. After making some decisions about what would be called clinical research and looking at which study sections review it, we have been able to see that those applications are doing less well in the review process.

Now, the question is, why do they not do as well as other types of grants?

There is certainly one school of thought, represented by some clinical as well as basic investigators, who feel that, in general, the clinical research applications are often less well crafted, with less attention given to control groups, less good design and less hypothesis-driven research. Under those circumstances, I think what we need to do is to work at the grassroots level to improve our training of clinicians who want to become scientists, to try to teach investigators with clinical backgrounds how to prepare a grant application that will be truly competitive. It is in that direction that I would prefer to direct our attention.

DELAYED OBLIGATIONS

Senator MACK. I appreciate your comments with respect to this issue. I will look forward to following up with you over time, and see how this is working out. But I appreciate the comment.

The last question that I have has to do with delayed obligations. Of the \$517 million increase for the National Institutes of Health, roughly \$120 million of the amount is in delayed obligations. And my understanding is that there were no delayed obligations in the 1994 appropriations bill. What assurances have you been given that this funding will be used for research grants? Do you believe these delayed obligations could have an impact on the funding level for NIH in fiscal year 1996, as well?

Dr. VARMUS. I do not believe we have any reason to feel that that would be the case. We expect that money to be spent. And it will just affect those grants that were reviewed later in the year.

Senator MACK. So, you do not believe that the delayed obligation amount is going to be any problem for you?

Dr. VARMUS. It puts us at the risk that Senator Harkin mentioned. But, aside from that, I think that it falls within our ability to manage the budget authority we have been given.

Senator MACK. Well, again, I welcome you here.

Dr. VARMUS. Thank you.

Senator MACK. I am very impressed with your opening statement, and I look forward to working with you.

Dr. VARMUS. Thank you, Senator.

OFFICE OF AIDS RESEARCH

Senator HARKIN. Thank you, Senator Mack.

Dr. Varmus, just a couple of follow-up questions. One has to do with AIDS, and Dr. Paul's office there. The Revitalization Act set up the Office of AIDS Research for developing a coordinated budget on HIV research. It now totals \$1.378 billion this year.

Dr. VARMUS. Correct.

Senator HARKIN. I guess my question really is how that was formulated, the process, the degree of cooperation within individual Institutes, how that was formulated with them. Can you just give me some idea of how it was prepared?

Dr. VARMUS. Dr. Anthony Fauci, the former Director of the Office of AIDS Research and still the Director of the National Institute of Allergy and Infectious Diseases, was the negotiator in the formu-

lation of the budget. He made use of five coordinating committees that addressed five major themes in AIDS research: behavioral aspects, vaccines, therapies, pathogenesis, and epidemiology.

Those five coordinating committees developed a 5-year plan. In the context of that 5-year plan, Dr. Fauci, as the head of the Office of AIDS Research, negotiated with each of the Institute directors to develop an AIDS budget for each Institute.

And, as you know, virtually every Institute, Center, and Division has an AIDS budget that has programmatic content and that is consistent with the 5-year plan and with the suggestions of the coordinating committees.

We expect very much the same kind of process to go on next year. But, of course, there is new leadership, with Dr. Paul having arrived in the Director's office. We are currently making some additions to the coordinating committees. Committee members will be meeting to discuss the 1996 budget the end of March. We expect the process to operate fundamentally in the same way. That is, negotiation with Institute directors would be based on the advice provided by our coordinating committees.

FUNDING OF AIDS RESEARCH

Senator HARKIN. I guess there was some concern in the past couple of years that with the huge increase in the amount of money that we are putting into AIDS research and the fact that it was disbursed through, I guess, you said through just about every Institute, NCI getting the most—

Dr. VARMUS. No; the National Institute of Allergy and Infectious Diseases receives the largest share of the AIDS budget.

Senator HARKIN. Yes; I see. NCI is second.

Dr. VARMUS. The National Institute on Drug Abuse has the third largest AIDS budget.

Senator HARKIN. But, anyway, my point is, all through out.

Dr. VARMUS. Right.

CONTINUATION OF COSTS FOR AIDS RESEARCH

Senator HARKIN. There is some concern about this huge input of money, and that there was overlapping research; that it was not being spent wisely; that we needed this coordination. And that is how all this came about. We were concerned about the continuation costs and what percentage of the AIDS budget involved continuation costs, and whether or not you defined continuation costs.

Dr. VARMUS. Yes; we have. Continuation costs will be associated with ongoing AIDS research activities and will be delivered, as the law instructs us, within 15 days after the funds are delivered to NIH.

New and competing activities money for new awards will be allocated to the Institutes within 30 days after the money is received in the Office of the Director.

I should say that, of course, as with all Federal agency budgets, a large percentage of the budget is already committed. That varies from year to year with the AIDS budget, in part, because one of our large and most expensive programs, a therapeutic trial program called the AIDS clinical trials group [ACTG]. The ACTG will

come up for renewal in 1996. The shift of such large, costly grants from noncompeting to competing status causes some unevenness in the amount of commitment. But between 80 and 90 percent of the AIDS budget is committed each year.

FUNDING FOR BASIC AIDS RESEARCH

Senator HARKIN. How much of that is for basic biomedical research?

Dr. VARMUS. I am not sure exactly what the number is, but I would imagine it is roughly 60 percent.

Senator HARKIN. Could it be more?

Dr. VARMUS. Well, it depends on how you define basic research. But we have a serious commitment to finding effective drugs and vaccines, and I would not want to shirk that responsibility. As you know, within the portfolio of AIDS research, there is a tremendous amount of research going on in basic virology and immunology, as is appropriate. And, of course, we are leaving it to the coordinating committees to look closely at achievements, and opportunities and requirements for this program in succeeding years.

I would not want to prejudge their conclusions.

Senator HARKIN. I understand.

I think there has been some concern expressed to me that perhaps we are racing too far or too much on AIDS research, in terms of some trials and tests, without really looking more to basic research, fundamental, basic biomedical research. I do not know if that is well-founded.

Dr. VARMUS. I do believe we have a large investment in the basic components in our program. I point out that although it may look to you as though the dollar amount increment for AIDS research is large for this year, it is only 6 percent. And given the magnitude of the problem, the remarkable scientific opportunities, the amount of research within the AIDS portfolio that is having an impact on many other aspects of disease—cancer, gene therapy, basic cell biology, understanding of the immune system—this is a very good investment in my view.

Senator HARKIN. Well, you are right about next year. I guess I look back over the last 4, 5, or 6 years, and what has happened, in terms of the amount of money going into AIDS. There has been a tremendous increase.

Is the way the OAR budget is prepared the only way to implement the law that we passed here? Are there any options?

Dr. VARMUS. We believe that we are following the instructions of the law to the letter, and that this is the way it needs to be administered.

INDIRECT COST PAUSE

Senator HARKIN. The last question I had, Dr. Varmus, has to do with the pause, the 1-year pause. Can you tell me how that is going to work, and what do you think the effects will be of that 1-year pause?

Dr. VARMUS. As you know, this is an addition to the budget that we were introduced to at the very last moment. I am not sure I

have a full understanding of it. Mr. Williams is here to help out if we have a problem in explaining it to you. [Laughter.]

My understanding is that we will be giving out the number of grants we would normally give out, but the direct costs will not be affected. Institutions that receive at least \$10 million in grants in 1994 and have an increase in indirect costs in 1995 will be asked to reserve their unliquidated obligations and to apply them to 1995.

Exactly how that is going to be done at various institutions, I think, is open to question. But those are the instructions we have received from the Department and the OMB.

As you know, this is in response to a need to fulfill our obligation to meet caps on discretionary spending.

EFFECTS OF INDIRECT COST PAUSE

Senator HARKIN. I had a letter here from Cornelius Pains, the president of the Association of American Universities. And as I read through it, I was struck by his comments in terms of how this might penalize a university that really had increased its research significantly and was making significant discoveries, and where they had gone out and hired new people.

As he said here: "One outstanding scientist can do a hundred or a thousand times more than someone who is almost as good." That struck me as interesting.

Dr. VARMUS. You are not asking me to respond to that, are you, Senator? [Laughter.]

Senator HARKIN. No; but he said that if a university had gone out and hired such people and had really increased their research, that they are the ones that are penalized, rather than maybe one that had sort of stayed level and maybe gone down a little bit. What say you to that argument? Is that a legitimate argument?

Dr. VARMUS. That sounds consistent with what I understand to be the rules by which this measure will be applied.

Mr. WILLIAMS. Mr. Chairman, if I might just point out, obviously, it will have a differential impact, as you pointed out, on different universities. But I think it is worthwhile noting that what is envisioned here is not a permanent, but a 1-year policy. And during this period of time, the Office of Science and Technology Policy and others would be involved in looking at a longer-term approach to indirect costs that would perhaps avoid some of the problems which you mentioned.

So, we are not talking about here a permanent policy, but one that applies for 1 year, with a study to show the way toward a longer-term, more stable policy in this area.

Senator HARKIN. So what you are saying is that plans are this is just a 1-year event and during that 1 year the universities have to eat those costs? You certainly cannot give me assurances that we will not have to do this again next year?

Mr. WILLIAMS. No; but the policy as currently stated is a 1-year policy. It's not proposed that the policy will last beyond that 1 year.

Senator HARKIN. Just again I'm interested in the impact. Can we get through 1 year of doing this? Will universities be able to absorb this for 1 year? That is I guess what I am wondering.

Dr. VARMUS. The view is shared pain, that many programs across the board are being cut back in response to discretionary

funding caps, and that there will be pain and the pain will be more widely shared.

LONG-TERM COST SAVINGS OF BIOMEDICAL RESEARCH

Senator HARKIN. Well, I understand that.

One last sort of general question. One of the arguments I hear all the time about our proposed health research funds and about putting more money into health research is that it just leads to costing more money, it leads to new devices, new treatments, and you just spend more money; it really does not save money.

I guess I just have a general question. I am sure you have heard these arguments before. What is your view of that argument and how do you feel? Does medical research contribute to long-term cost savings or does it not?

Dr. VARMUS. There are a number of ways to respond to that, Senator. First of all, we do generate new technologies for improving health. The expense comes in the way those are applied, and I do not think they are always applied in the most efficient and cost-saving manner.

That said, there are many things that we propose and see put into practice that are clearly cost-saving. My favorite example comes from the work of the National Institute of Dental Research. The use of fluoride to prevent dental caries is a development which alone saves several billion dollars a year to the taxpayer and to the purchasers of medical and dental care.

We have put together, as you know, a small booklet that describes a number of advances in medical science that have had distinct effects on saving dollars through more efficient and more effective care.

The analysis of the economic consequences of what we do is a difficult one. It is clearly cheaper in some ways for someone to die of a heart attack at the age of 60 than to live to 85 and undergo care for Alzheimer's disease. We cannot weigh that kind of distinction.

My own feeling is that if you respond to our new ability to save 1,000 newborns from infection with HIV, to save a diabetic from late stage complications of renal disease or, to diagnose colon cancer at a time when it can be cured, we do not need to do a cost-benefit analysis. The vast majority of people would endorse spending for medical research to protect people from diseases that cut them down at early ages.

I think there is no doubt that biomedical research has a beneficial effect and a cost-savings effect in many sectors. A complete fiscal analysis has always been a very difficult one to make.

Senator HARKIN. I appreciate that booklet. I had seen it before and I think it is good. We have got to start fighting back, I think, with facts, with data.

Of course, my views on this are well known. I am just looking for different ways of saying it and stating that type of an argument, because I am convinced that if you really want preventative care and quality care we have got to put the money into research. It has been proven time and time again.

Those who say, well, it provides more treatment and, therefore, more people partake of it, it costs more money, I guess the answer is basically what you said: Yes, well, but how do you weigh that

in terms of a person's life? And I quite frankly think that the benefits to society in terms of keeping a person healthy longer, in terms of their work productivity and what they contribute to the society, far outweighs whatever savings society might get if that person were just to simply die.

So I think that is how we have to look at it.

Senator MACK. Mr. Chairman.

Senator HARKIN. I am sorry. Senator Mack.

Senator MACK. I got a reprieve.

Senator HARKIN. The floods did not come?

Senator MACK. There is still talk of it, but your area of the country is safe, I understand.

Senator HARKIN. It must be Kerrey from Nebraska is offering it.

EARMARKING

Senator MACK. I wonder if I may follow up. I was thinking through your response to my question about earmarks. I think I need to be more direct, because it sounded—and maybe I misunderstood you, but it sounded to me like you were inviting us to earmark. Is that right?

Dr. VARMUS. No. [Laughter.]

But I was telling you the way we can live with the earmarks as a way of doing some public education and using them as a way of thinking through what NIH is doing.

Senator MACK. What that is saying to me is that, as a politician who maybe should be more concerned than you are with perceptions, that maybe I should do exactly that, that we ought to engage on this committee in earmarking.

Dr. VARMUS. I think if we did our job in the most effective manner we would convince you and the public that we were doing what we should be doing and that we should be using our appropriations in our best scientific judgment.

Senator MACK. Then are you saying to me that we should not be earmarking?

Dr. VARMUS. That is correct.

Senator MACK. Thank you, I think. [Laughter.]

Senator HARKIN. But we should have an ongoing dialog about it.

Dr. VARMUS. Yes.

Senator HARKIN. And about where science is headed and what type of research. Again, I respect that view and we certainly do not want to be involved in earmarks. But as you said, and I think quite correctly, Dr. Varmus, the people who pay our salaries, your salaries, they have a right to be heard out there, and I think there has been proof positive in the past that perhaps, as we all are wont to do, we are going down a certain path and perhaps we do not see some of the side roads. We go down one way and we lose perspective, and I think it is quite clear that in the past women's health issues have not been part of the mainstream of investigative research at NIH.

I say that quite forthrightly.

Dr. VARMUS. Senator, could I make a point about that I probably should have made in response to Mr. Reid?

Senator HARKIN. Yes.

Dr. VARMUS. Which is that, although we do have initiatives in this area and I strongly endorse the concept of paying careful attention to the health of women, I would also point out to you that the vast majority, over 87 percent of what we do, is not gender-specific research. It applies both to men and to women.

Our efforts in basic cell biology, for example, and in many other areas is not pertinent to one or the other. When we study cancer in the breast, for example, we are learning things that apply to cancer of the prostate, a disease which actually is less accessible to many of the conventional techniques that have been developed over the years.

So when we compare the breast cancer allocation, our expenditures in the breast cancer area, which as I mentioned total around \$384 million, to our allocations for prostate cancer, which are in the range of \$60 to \$70 million, the denominator should not be the number of patients who have the diseases. The allocations should be viewed in accord with the scientific opportunities for making gains in these areas.

In addition, it is very hard to make boundaries between the study of one cancer or the other. Much of what we do in cancer research, which is still in the highly exploratory area, especially in the basic component, may be applicable to one cancer or the other. This relationship is difficult to determine.

I think we need to be careful about how we divide up our computations.

DETERMINING SCIENTIFIC PRIORITIES

Senator MACK. Unfortunately, the use of numbers are very easy for different groups to use. I am not going to do that this morning, but I think what I am trying to say to all of us is that we ought to be sensitive.

I am hearing from constituency groups who are saying: How come all those other groups are getting attention and we are not. I think it would be beneficial to the scientific community to understand that is beginning to swell up, and we need to be thinking about ways to address that, so in fact you can make the best decisions based on scientific data about where to spend that money.

I think it would be foolish of us to try to push this issue aside, because it is building out there.

RECRUITMENT OF DIRECTOR FOR OFFICE OF BEHAVIORAL RESEARCH

Senator HARKIN. I want to second what Senator Mack said. As Chairman, I also hear from different groups and individuals, and we have to be sensitive to that. That is why I say, while we do not want to be involved in earmarking, I think there has to be an ongoing dialog about what our constituencies out there are saying and what people would like us to be doing with their money. That is legitimate democracy.

So we have to pay attention and be responsive, and I think you have been, and NIH has been, at least over the last few years that I have been working with NIH. And I think all the directors have been very responsive to inputs from the public.

Thank you very much, Dr. Varmus. I appreciate your being here.

Oh, I just have one last thing. I want to ask about the Office of Behavioral and Social Research and the appointment of a director to that.

Dr. VARMUS. This is one of our major priorities. We are in the process of getting the office chartered. We will be initiating a search as soon as we have all the paperwork back from the Department of Health and Human Services. We have allocated a budget for the office. Dr. Kirschstein, when she was Acting Director, met with a number of representatives from behavioral and social science societies in order to get some ideas about how the office should be serving that community and to discuss possible candidates for advisory boards and research communities.

So things are very much in motion.

Senator HARKIN. It is moving?

Dr. VARMUS. Yes.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

EARMARKING

Question. In my opening statement, I spelled out the full details of the President's fiscal year 1995 budget request for the National Institutes of Health. Specifically, of that \$517 million increase for NIH, some \$221 million is earmarked for the Administration's targeted research program. Are my numbers correct, Dr. Varmus? Is this a healthy trend in budget for NIH and for medical research in general?

As I stated in my opening statement, removing these targeted increases reduces the increase for the rest of NIH to just 2.8 percent, less the projected 4.1 percent medical inflation index for next year.

Are my numbers correct, Dr. Varmus? Is this a healthy trend in budgeting for NIH and for medical research in general? Does this contribute to a balanced research program?

Answer. Of the \$517 million increase included for NIH in the fiscal year 1995 President's Budget, a total of \$209.8 million has been earmarked for the Administration's targeted, high priority research programs. These major areas of research are as follows: tuberculosis, women's health, high performance computing, breast cancer, minority health, and AIDS.

In my opinion, NIH research priorities should be identified within the professional scientific community. Within the panoply of research activities that comprise NIH, basic science is fundamental to discoveries and breakthroughs that enable us to extend the human life span through the prevention of such deadly diseases as AIDS and tuberculosis, and improve the quality of life by delaying the onset of diseases such as Alzheimer's and osteoporosis. The current process of identifying investment areas is a way of making progress toward specific goals that we would like to pursue. At the same time, it is up to NIH to educate the general public about the benefits of basic research. The public needs to know that funding for basic research is the foundation for success in the prevention and elimination of many specific diseases including breast cancer, Alzheimer's disease, and tuberculosis.

DELAYED OBLIGATIONS

Question. My opening statement outlined my concerns with some of the Administration's proposed budget gimmicks to save some \$134 million in outlays in NIH's budget for next year. For budget authority, that translates into more than \$300 million in budget authority.

Dr. Varmus, are my concerns warranted?

Answer. I have every reason to believe that the Administration's cost savings proposals would have no impact on NIH's budget authority in fiscal year 1995. The Administration proposes a temporary freeze (pause) on overhead costs at the fiscal year 1994 level and a delay in fiscal year 1995 obligations. The pause in indirect costs is a temporary one year policy that will allow the President's science advisors, with input from affected institutions, to make recommendations for improving management of overhead costs associated with research grants. Institutions that receive at least \$10 million in grants in 1994 and will have an increase in indirect costs in fiscal year 1995 will be asked to reserve their fiscal year 1994 unliquidated obligations and apply them to their requirements for fiscal year 1995. This provision will not affect grantees who have not received funds prior to fiscal year 1995 or grantees who claim overhead payments below their fiscal year 1994 level.

Th: Administration also proposes to reduce outlays by approximately \$56 million in fiscal year 1996 by delaying \$121.4 million in obligations until September 19, 1995. The Administration's intention is to provide savings in fiscal year 1995 by changing the timing of outlays incurred without affecting the total amount of obligations. The delay of obligations will be implemented through the NIH extramural grant and contract mechanisms.

The most effective means to delay obligations will be to defer the entire twelve-month award of new and renewal grants until September, 1995. The greatest proportion of the delay will be realized in the research grant mechanisms, especially construction grants which are typically funded in September and have historically produced slow outlays.

RECOMMENDATIONS OF INTRAMURAL REVIEW PANEL

Question. It is my understanding that the House Appropriations Committee in its report accompanying the fiscal year 1994 Labor, HHS, and Education Appropriations bill, requested a report from the NIH on various aspects of its intramural program. That report would deal with such questions as the balance between the NIH's extramural and intramural programs and specifically, the size and cost of the proposed construction and/or renovation of the clinical center at NIH's Bethesda campus.

Dr. Varmus, I understand that the task force assigned for studying this issue is wrapping up its report? What can you tell us about some of the preliminary conclusions of this report?

Answer. In response to the Congressional directive, the NIH initiated a two-phase review process that began in July 1993 with a trans-NIH Intramural Program fact-finding effort by an internal committee. The fact-finding culminated in a draft report and extensive data which described the nature and operation of all aspects of the intramural research programs. The second phase of the NIH response to the Congressional mandate was the actual evaluation of the intramural programs and was carried out by a group of ten External Advisors with expertise in basic research, clinical research and the management of research. The Committee was co-chaired by Gail Cassell, Ph.D., Professor and Chairman of the Department of Microbiology at the University of Alabama at Birmingham, and Paul Marks, M.D., President and Chief Executive Officer, Memorial Sloan-Kettering Cancer Center. The remaining members of the committee were: Michael S. Brown, M.D., University of Texas; Gerald D. Fishbach, M.D., Harvard Medical School; Elizabeth F. Neufeld, Ph.D., UCLA School of Medicine; Arthur H. Rubinstein, M.D., University of Chicago; Maxine F. Singer, Ph.D., Carnegie Institution; Kenneth I. Shine, M.D., Institute of Medicine; P. Roy Vagelos, M.D., Merck & Co., Inc.; and James H. Wyche, Ph.D., Brown University.

After assessing the information gathered through the initial fact-finding phase, the External Advisors concluded that, rather than review specific research programs in the individual Institutes and Centers, a more effective use of their time would involve evaluating the process or processes used to review the quality of the research and to determine the balance between intramural and extramural programs. Consequently, the External Advisors undertook their evaluation by focusing on three major goals:

- (1) To evaluate the process or processes currently employed to review the quality of the intramural programs at all levels, from preparation of trainees for research careers through independent scientific achievements to the performance of the Scientific Directors;
- (2) To evaluate the process for allocating funds between the extramural and intramural research programs; and
- (3) To evaluate what new and renewed Clinical Center research facility is required to assure continuing high quality research and productivity in the future.

The external advisory group is currently in the process of revising its full report, which I expect to receive prior to the House hearings scheduled for April, 1994.

I have received and reviewed, however, an executive summary of the Committee's report. An early reading of that executive summary indicates that the recommendations in the report propose more uniform and consistent processes across all Institutes for setting priorities and ensuring the continuing quality of the intramural research programs. The Committee also makes several recommendations related to ensuring the continued quality and productivity of intramural scientists, scientific directors, and training programs. Also, there is agreement that the Clinical Center should be renewed. However, funds for such a purpose should not be obtained at the expense of the extramural research program or the quality programs in intramural research.

The internal NIH review effort and the recommendations of the External Advisors will form the basis of substantive changes in the way in which intramural research is reviewed and in our recommendations concerning Clinical Center renewal.

SUPPORT FOR DECADE OF THE BRAIN ACTIVITIES

Question. For fiscal year 1994, the Conferees agreed to appropriate \$7.5 million for the NIH Directors Discretionary Fund. In approving these funds, the Conferees, while not specifying a funding level, believed that a portion of this amount "should be allocated to Decade of the Brain activities."

Dr. Varmus, what's the final total for the DDF for fiscal year 1994? How much of that total will be allocated for Decade of the Brain activities? Could you provide for this Committee a detailed allocation for how you intend to use the Discretionary Funds provided you for fiscal year 1994?

Answer. As a consequence of the rescission of \$18,200,000 from NIH in fiscal year 1994, the Director's Discretionary Fund has been reduced to \$6.5 million in fiscal year 1994. This level of funding represents a thirty-nine percent decrease from the President's Budget Request of \$10,661,000 for this fund. Currently, I plan to direct \$4 million of the fund to Shannon Awards. As you are aware, these awards are targeted to young scientists endeavoring to launch independent careers and to a number of established scientists who, while continuing to make significant scientific contributions, are finding it increasingly difficult to obtain grant renewals. The program provides a limited award to investigators whose applications have been judged as highly meritorious by the usual NIH peer review procedures, but which fall below the individual institute funding cut-off line. Investigators do not apply for Shannon awards, but are selected based on the research plan and potential for future success in the award process. I am sure that many of these applications will propose research that furthers the goals of the "Decade of the Brain" initiative. However, it is impossible to identify the exact amount of funding that will be directed to that area at this time, since these awards are made late in the fiscal year.

Additional uses of the DDF this year are: \$50,000 to support a scientific speakers series, \$170,000 to initiate the Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds which was authorized in the NIH Revitalization Act of 1993, and \$1,000,000 to augment NCI efforts to identify the breast cancer gene. There remains about \$300,000 uncommitted in this fund at this point in time.

SUCCESS RATES

Question. What is the success rate for the NINR and for NIH as a whole? Why is the success rate for NINR so much lower? And what can be done to correct this difference in fiscal year 1995 and beyond?

Answer. The success rate for the NINR under the fiscal year 1995 President's Budget is estimated to be 12.2 percent; the estimate for NIH overall is 27.0 percent. The reasons for the gap between NINR's success rate and the NIH average are historical and reflect the intense competition for research funding. The impact of this low success rate has been lessened somewhat by NINR's effort in undertaking collaborative projects with other ICD's. Given their unique contributions, I am encouraging NINR to continue to leverage resources with the other Institutes.

COMMUNITY-BASED CARE

Question. What is NINR doing to provide practice knowledge for community-based care focused on health promotion and disease prevention, as emphasized under health care reform?

Answer. Prevention strategies and community-based care will be a focus of a NINR initiative in fiscal year 1995 as we implement the next priority of the National Nursing Research Agenda. This initiative will expand the NINR research

portfolio to include studies on community-based health care models targeted to primary health care intervention strategies for vulnerable and underserved populations in rural and inner cities. The goal will be to test models that have the potential of achieving culturally sensitive quality clinical health care services for these at-risk populations in a cost effective manner.

This initiative builds on a number of studies currently supported by NINR. Approximately 45 percent of the NINR research portfolio is directed at health promotion/disease prevention with particular emphasis on child and adolescent health, reproductive health, elderly health, and chronic and recurrent health conditions. Examples of these studies include a successful program to increase colo-rectal cancer screening in socioeconomically disadvantaged, poorly educated elderly in community meal sites. Early cancer screening is a fruitful prevention strategy because an estimated \$8 is saved in treatment costs and lost earnings for every dollar spent on early detection of cancer. Another study focused on the prevention of cardiovascular disease in high-risk rural children. Using a nurse-designed educational program taught by classroom teachers, these children experienced a significant drop in cholesterol levels and measurements of body fat. In addition, the children's knowledge about basic cardiovascular principles, exercise, smoking, and nutrition improved significantly after the classroom instruction.

SUPPORT FOR SOCIAL AND BEHAVIORAL SCIENCES

Question. What role will the social and behavioral sciences play in fulfilling the mission of NIH under your stewardship?

Answer. The establishment of a central office for behavioral and social sciences research within the immediate Office of the Director will provide the infrastructure needed to achieve fuller integration of the behavioral and social sciences into the broad spectrum of medical sciences at the NIH.

Working closely with scientists in many specialized areas—intramurally, extramurally, and internationally—the NIH will foster a solid program of basic research to identify those individual, group, social, and environmental determinants of human behavior that contribute to the Nation's public health problems and apply this information to promote healthy lifestyles and to reduce the morbidity and mortality from the leading causes of death.

Question. It has now been nearly nine months since Congress authorized the Office of Behavioral and Social Sciences Research [OBSSR] at NIH, yet it remains unstaffed, unfunded, and with a mandated report to Congress, unwritten. What are your plans for expediting the establishment and full operation of the OBSSR?

Answer. The establishment of this Office and the selection of its Director are underway. Documents requesting the establishment of the Office await approval by the Public Health Service and the Office of the Secretary.

For fiscal year 1994, \$150,000 has been allocated to fund salaries to support two professionals and one support staff. For fiscal year 1995, \$2,500,000 is allocated for OBSSR and reflected in the NIH budget request under the President's Budget.

At Mr. Waxman's request, an interim report describing the steps taken by NIH to establish the OBSSR was forwarded on February 25. Once appointed, the Director, OBSSR, will develop and submit to the Congress, as mandated, a comprehensive report on the extent to which the NIH conducts and supports research in the behavioral and social sciences.

GRANTS REVIEW PROCESS FOR FORMER ADAMHA INSTITUTES

Question. As you know, the National Institutes of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism were brought into the NIH in October 1992. Because the peer review systems of the Institutes had been developed over time to meet the specific and complex needs of the alcohol, drug abuse and the mental health fields, the law provided that these peer review systems and the Institutes' scientific advisory committee would be transferred with them to the NIH, and be utilized through fiscal year 1996. Could you bring us up to date on the grants review process for these institutes after fiscal year 1996?

Answer. Background: Prior to bringing the research components of three former ADAMHA Institutes into the NIH, the review policies and procedures of those three institutes had evolved along a somewhat different path from those of NIH. These differences were largely a function of their size, organizational structure, and to some extent include philosophical differences in approaches to peer review. Traditionally at NIH, the initial peer review process has occurred in either of two settings. The first and largest focus for initial review is within the Division of Research Grants—a centralized NIH component which provides expert scientific review in

study sections organized largely according to research disciplines associated with the biomedical and behavioral sciences rather than along programmatic lines of an individual institute or center (IC). The other place where initial review may occur is within individual NIH IC's, where certain applications, often submitted in response to a specific solicitation, are reviewed by committees with "customized" membership to meet specific program needs. Prior to fiscal year 1993, DRG reviewed approximately 80 percent of all applications assigned to the NIH and, importantly, nearly all investigator-initiated regular research grant applications. In the former ADAMHA institutes there was no centralization of initial review as in DRG; each of the three institutes has conducted the initial peer review of all applications assigned (by DRG) to that organization. Prior to October 1992, a transition task force was established to explore similarities and differences in policies and practices, and to encourage collaboration and interaction between and among the IC's.

Current status: Although the law provides for the maintenance of former ADAMHA review procedures through fiscal year 1996, important changes are occurring which will provide for an orderly transition to an NIH wide system that will accommodate the needs of all IC's. From the beginning, appropriate senior staff from the NIMH, NIDA and NIAAA have been appointed to all NIH committees, including the Extramural Program Management Committee, the Review Policy Committee as well as others.

Several examples of ongoing and completed actions include:

1. In the late 1980's the NIH decided to expedite the review of individual fellowships to provide additional time for applicants to plan their next career step. ADAMHA did not follow this practice. Through discussion and adjustment of timetables, all NIH fellowship applications now receive an expedited review.

2. Following the establishment of the NIH Reviewers Reserve, a cadre of experienced reviewers, ADAMHA developed a similar program. The DRG now maintains a single NIH Reviewers Reserve as a resource for all NIH components.

3. The DRG has served as the central receipt point for research grant applications submitted to most of the PHS, including the former ADAMHA. Senior Scientific Review Administrators serve as Referral Officers, responsible for assigning research grant applications to the most appropriate initial review group (IRG). Two additional Referral Officers, highly trained in the behavioral sciences, now assign applications to NIAAA, NIDA, and NIMH, and to the most appropriate IRG in the Institutes or DRG.

4. In responding to the Executive Order to reduce the number of Federal Advisory Committees, a more streamlined organizational structure was developed in the DRG. This has resulted in an increased capability to shape the expertise of study sections, as well as an increased flexibility to establish new groups.

The future: It is anticipated that, in time, the review procedures for NIAAA, NIDA and NIMH will not differ significantly from those of other NIH IC's. Investigator-initiated applications for trans-NIH award mechanisms will be reviewed within the Division of Research Grants, NIH. A fundamental tenet of the initial review process at NIH is that the assessment of scientific merit be offered by experts in the field. This underlying principle will not be compromised by accepting additional, central review responsibility. It will require the establishment of some additional study sections, as well as readjustment of existing ones.

NIH is committed to engaging reviewers who represent the best, most productive scientists from all disciplines in the biomedical and behavioral sciences. By developing study sections with commonalities in expertise, but with broader scientific experiences, there will be an increasing awareness and appreciation for new and emerging developments in biomedical and behavioral research.

PREVENTION RESEARCH FOR MENTAL DISORDERS

Question. Using definitions of prevention and prevention research developed in the Institute of Medicine's 1994 report entitled "Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research", (1) what is the current level of prevention research for the prevention of mental disorders at the NIH; (2) identify each Institute's funded programs for the prevention of mental disorders, separately accounting for universal, selective and indicated preventive intervention; (3) what fraction of the overall prevention research involves co-funding between Institutes?

Answer. The NIH definition of prevention research, a definition that took three years to finalize and ultimately became the PHS definition, is different from the definition applied by the IOM in its 1994 report on prevention of mental disorders. For example, the NIH definition is broader in scope than the IOM definition (see attached NIH definition). The IOM definition is devised within a mental health frame-

work and as stated in the IOM report, “* * * the term prevention is reserved for only those interventions that occur before the initial onset of a [mental] disorder.” Also, the IOM terms “universal,” “selective,” and “indicated” preventive interventions will have to be reviewed in the context of current NIH classification systems. The full extent of definition differences, and the implications of applying the IOM definition to NIH mental-health-relevant prevention studies, will require extensive review, discussion, and agreement among the Institutes, Centers, and Divisions [ICD’s]. For this reason, the NIH will need additional time to supply current levels of prevention research for the prevention of mental disorders at NIH, using the definition and prevention categories developed by the IOM Advisory Committee.

Subsequent to the release of the IOM report, the Chairman of the NIH Prevention Coordinating Committee established a Subcommittee on Mental Health to address the IOM report recommendations; the Subcommittee will also address the questions and issues raised by the Senate Appropriations Committee. The Subcommittee membership consists of representatives from the following Institutes: NIMH, NHLBI, NCI, NIAAA, NIDA, NICHD, NIA, NIEHS, and NINR. The Subcommittee members will work with ICD representatives to obtain data on mental-health-related prevention studies including basic research and interventions, will assess the levels of funding including co-funded studies among the ICD’s, and will report back to the full Prevention Committee. Once the funding levels are agreed upon by the ICD Prevention Coordinators, this information will be included in the Prevention Committee’s “Mental Health Studies Report” anticipated for completion by Fall 1994.

Question. In addition to the co-funding of research projects, what efforts have been made to coordinate research efforts for the prevention of mental disorders across the Institutes? I understand that a subcommittee of the NIH Prevention Coordinating Committee has been formed to address the IOM report, especially the recommendations from a NIH-wide perspective. Can you please submit a copy of their report to the committee when it becomes available? What efforts have been made to coordinate research efforts, including co-funding of projects, with other DHHS agencies, such as the Substance Abuse and Mental Health Services Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, as well as with other federal departments, such as the Department of Defense, the Department of Education, and the Department of Justice?

Answer. As soon as the “Mental Health Studies Report” is completed and approved by the NIH Prevention Coordinating Committee, the NIH will be pleased to submit copies of the report that will be based on the findings of the Subcommittee on Mental Health. One of the principal objectives of the Subcommittee will be to assess the current scope and level of effort across the Institutes in the coordination of mental disorders prevention research, and to develop plans for expanded collaborative efforts in the future.

Presently the NIH grants and contracts portfolio is cataloged on the basis of the existing NIH prevention definition that does not separately account for studies on mental disorders. Therefore, the ICD Directors will need to review and catalog their entire grant and contract portfolios, involving review of approximately 22,000 studies to identify projects or portions of projects which are mental-health related; this will require the efforts of ICD prevention coordinators, individual discipline and/or disease program administrators, planning officers, budget officers, and finally ICD directors. It is anticipated that the “Mental Health Studies Report” will be available in the Fall 1994. This report will also include a listing of all co-funded mental health projects, including those between ICD’s, other PHS agencies, DHHS, as well as other governmental departments.

FUNDING FOR IOM RECOMMENDATIONS

Question. As you know, the IOM committee recommended a \$50 million funding increment, but did not break this out by NIH institute or other agency. Some items are clearly intended for the National Institute of Mental Health (the child epidemiological study, population studies, mental health promotion study, and some fraction of training, preventive intervention centers, and preventive intervention research projects initiated by investigators). Other items are clearly not for NIMH (the council or office for coordination and dissemination, and some fraction of training, prevention research projects and perhaps preventive intervention research centers). Some of these funds would go to other NIH Institutes (e.g., NIDA, NIAAA, and NICHD), some to other parts of the federal government (e.g., CDC, SAMHSA, ACYF, HRSA, Department of Justice, Department of Defense, Department of Education), and even to the states through block grants (some fraction of training and research projects aimed at improving evaluation of ongoing programs)? Could you

submit to this committee your best estimate of funds that would be necessary within NIH to implement the IOM committee's recommendations, according to specific institutes and line items?

Answer. The "Mental Health Studies Report" will include funding estimates within NIH, and the individual ICD's, necessary to implement the IOM committee's recommendations once these estimates have been approved by the Director of NIH, the Secretary of Health and Human Services, or the President. It is anticipated that most of the NIH institutes will have research studies relevant to an agreed-upon definition for mental disorders.

NATIONAL INSTITUTES OF HEALTH

DEFINITION OF PREVENTION

Prevention research.—Narrowly defined, prevention research includes only that research designed to yield results directly applicable to identification of risk, and to interventions to prevent disease or the progression of detectable but asymptomatic disease.

Pre-Intervention: Identification of risk factors for disease and risk assessment; development of methods for identification of disease controllable in the asymptomatic stage; and refinement of methodological and statistical procedure for assessing risk and measuring the effects of preventive interventions.

Intervention: Development of biologic interventions to prevent disease occurrence or progression of asymptomatic disease; development of environmental interventions to prevent disease occurrence or progression of asymptomatic disease; and conduct of field trials and demonstrations to assess interventions and to encourage their adoption.

Some interventions may be applicable to primary prevention as well as to disease treatment (e.g., diet and exercise as components of rehabilitation for coronary heart disease). Research into such interventions is considered prevention research.

Prevention-relevant research.—More broadly defined, prevention research also includes research with a high probability of yielding results that will likely be applicable to disease prevention or health promotion. Included are studies aimed at elucidating the chain of causation—the etiology and mechanisms—of acute and chronic diseases. Such basic research efforts generate the fundamental knowledge that contributes to the development of future preventive interventions.

QUESTIONS SUBMITTED BY SENATOR KOHL

THE NCHGR INTRAMURAL PROGRAM

Question. We have been hearing for several years about the importance of the NIH's contribution to the Human Genome Project which, as I understand it, is funded as an extramural grant activity of the National Center for Human Genome Research as well as through the Department of Energy. I also understand that the Center recently worked with the Department of Energy to update its five-year plan for the Project, pointing out that additional extramural funds would be necessary to achieve the Project's goals. What I don't understand is while the fiscal year 1995 Budget Request for the Center rises by 18 percent, or \$23 million, 79 percent of this increase goes for the Center's intramural program, not for the Genome Project. While many argue that we need more clinical work in gene therapy, don't we need to focus first on getting the basic genome information on which such therapy can be based?

Answer. You are right that we need basic genome information in order to develop effective gene therapy. However, the Human Genome Project has already generated so much basic information, that we would be remiss not to start using the information to benefit patients. For this reason, the intramural program of the NCHGR was developed. Both the extramural and the intramural programs of NCHGR are vital and will make tremendous contributions to biomedical research and human health.

The extramural program focuses primarily on basic research and seeks to analyze the structure of human DNA and identify the location of the estimated 100,000 human genes. The tools provided by this program have already made a substantial contribution to the mapping of genetic diseases and shortened considerably the time necessary to find human genes. The intramural program has a basic component as well, but also includes clinical programs focusing on genetic diagnosis and gene therapy. As you can see, the programs are quite complementary.

The increase requested for the intramural program stems from the fact that the program is new and still in its growth phase. It is expected to plateau in fiscal year

1995 at approximately \$40,000,000. It was imperative that a critical mass of research support and research investigators be established relatively quickly. This aided the program and the NIH in a number of ways, including recruitment of leading scientific researchers to the NIH, rapid program development, and economy of resource use. In no other way could the rich continuum from basic research to diagnostics to gene therapy with interdisciplinary exchanges of ideas be established. In addition, the Division of Intramural Research includes core facilities accessible to other Institutes and new programs for visiting scientists and trainees, as well as new programs in medical genetics and genetic counseling training programs.

The NCHGR's intramural program is an exciting and valuable addition to the NIH and worthy of strong support. It is already making valuable contributions to research on the NIH campus and across the country, as well as in the international research community.

NIH SUPPORT OF BIOMEDICAL SCIENTISTS

Question. How many biomedical scientists, both Ph.D.'s and M.D.'s are supported by NIH in fiscal year 1994? How many additional, or fewer, scientists will be supported by the fiscal year 1995 budget request?

Answer. The NIH supports Ph.D.'s and M.D.'s using several mechanisms. The competing and non-competing research project grants [RPG's] are the major source of support for extramural scientists. Earlier studies indicate that each RPG supports an average 1.38 full-time equivalent [FTE's] at the doctoral level. If staffing on grants has remained constant since the fiscal year 1990 study, we estimate that the NIH supported approximately 33,130 doctoral level scientists in fiscal year 1994 and expect to support approximately 32,970 in fiscal year 1995. This will be a reduction of approximately 160 doctoral level FTE's.

In addition to RPG's, the NIH supports Ph.D.'s and M.D.'s in training programs such as the National Research Service Awards [NRSA]. In fiscal year 1994, the NIH estimates that NRSA will support a total of 14,388 trainees and follows training in biomedical and behavioral sciences. Of these positions, approximately 7,849 support predoctoral training and 6,539 support postdoctoral training. Of the postdoctoral positions, approximately half of the supported trainees and fellows hold the Ph.D., while the other half hold an M.D. or comparable clinical degree. The President's Budget for fiscal year 1995 would allow us to support 14,341 training positions, a reduction of 47 positions from fiscal year 1994.

Within the NIH intramural research program [IRP] there were, in fiscal year 1994, approximately 3,600 doctoral-level scientists occupying FTE positions, and another 2,400 postdoctoral trainees. It is anticipated that as a result of the overall decrease of 411 FTE's at NIH in fiscal year 1995, about 300 fewer doctoral-level scientists would be employed within the IRP. This personnel loss is expected to be only partially compensated for by additional appointments of postdoctoral trainees.

REASONABLE PRICING CLAUSES

Question. Some have criticized NIH's use of "reasonable-price" clauses in Cooperative Research and Development Agreements [CRADA's], and assert that NIH is no longer able to attract research partners for some of its important cooperative work with industry. While some companies may choose not to accept such language in these agreements, are you still getting enough good-quality applicants that you are able to get the job done?

Answer. In testimony given to the Senate Select Committee on Aging on February 24, 1993, NIH recognized that there is a potential conflict between enhancing its research programs through partnerships and cooperative efforts with the private sector and a potential regulatory function suggested by the reasonable pricing clause. The NIH has found that some drug companies have chosen not to engage in CRADA's with the agency because of the presence of the pricing clause. In fact, a recent survey of NIH Institutes revealed that about a dozen drug firms had indicated that this issue constituted a major impediment to initiating CRADA's with NIH labs. We believe this survey may reflect industry-wide concern over the pricing clause. Even though many firms have entered into CRADA's with NIH, there is evidence that there may be a significant number of missed opportunities, in that companies may be unwilling to approach the NIH to discuss CRADA opportunities because of concern over pricing. Although NIH believes that, overall, it has engaged in CRADA's on a fair basis, it would be preferable if a wider range of partners were available in our attempt to transfer technology, as intended by the Federal Technology Transfer Act.

SOCIETAL IMPACT OF BIOMEDICAL RESEARCH

Question. We are constantly hearing how big an impact a particular disease has on society, but I have never seen a total of all these estimates. Could you please present a table showing all of the estimates of the societal impact of the diseases on which NIH ICD's conduct research in 1994? Please show the medical costs separately from the costs of lost productivity and other indirect effects. Also show the total of all these estimates, as well as any discount you think may need to be applied to that total to reflect duplication and overlap among the estimates. For comparison, please also indicate the total amount that the U.S. spends on health care in the year for which these estimates are made. Finally, provide total NIH spending on these diseases in fiscal year 1994.

Answer. No table exists in the precise format that you are requesting. However, you may find the attached table useful. This table allocates the 1991 personnel health care expenditures of \$660.2 billion to 14 different disease categories. It also provides estimates of the costs attributed to suffering from such diseases (lost productivity) based on morbidity and premature mortality.

DIRECT AND INDIRECT ECONOMIC COSTS OF ILLNESS BY MAJOR DIAGNOSIS, U.S., 1991

(In billions of dollars)

Diagnosis	Direct costs ¹	Indirect costs—			Total costs
		Morbidity ²	Mortality ³	Total indirect	
Cardiovascular diseases ³	\$114.4	\$16.3	\$58.3	\$74.6	\$189.0
(Involving blood clotting) ^{4,5}	28.2	4.4	16.4	20.8	49.0
Lung diseases ⁶	45.9	15.3	12.9	28.2	74.1
Blood diseases ⁶	4.5	.5	1.0	1.5	6.0
Diseases of the digestive system	76.9	4.0	10.1	14.1	91.0
Neoplasms	34.7	10.2	55.6	65.8	100.5
Mental disorders	31.1	15.7	3.2	18.9	50.0
Diseases of the nervous system	36.9	3.6	4.1	7.7	44.6
Diseases of the musculoskeletal system	33.8	18.1	.9	19.0	52.8
Diseases of the genitourinary system	30.2	1.5	2.3	3.8	34.0
Endocrine, nutritional, and metabolic diseases ..	23.3	3.0	6.6	9.6	32.9
Infectious and parasitic diseases	17.4	7.3	20.7	28.0	45.4
Diseases of the skin	19.5	.2	.2	.4	19.9
Other respiratory diseases	26.8	6.7	1.9	8.6	35.4
Other and unallocable	164.8	17.6	72.1	89.7	254.5
Total	660.2	120.0	249.9	369.9	1,030.1

¹ Direct costs are personal health care expenditures for hospital and nursing home care, drugs, and physician and other professional services. Totals for these four types of costs are estimated by the Health Care Financing Administration Allocation by diagnosis is based on statistics from the National Hospital Discharge Survey, the National Ambulatory Medical Care Survey, and the National Nursing Home survey of the National Center for Health Statistics and the Hospital Cost and Utilization Project of the Agency for Health Care Policy and Research.

² Morbidity estimates are obtained by multiplying 1980 estimates by 1.77, an inflation factor calculated from Bureau of the Census data that reflects the 1980-91 change in mean earnings.

³ Mortality estimates are obtained by multiplying 1990 mortality estimates by two factors, a 1985-91 inflation factor (1.29) and an individual factor for each cause of death derived from the number of deaths in 1991 divided by the number in 1990.

⁴ Includes congenital cardiovascular disease.

⁵ Based on NHLBI definition of blood clotting diseases based primarily on proportions of morbidity and mortality statistics for acute myocardial infarction, cerebrovascular diseases, and diseases of arteries.

⁶ Does not include lung cancer, leukemias, or pulmonary heart disease.

Notes: This table was taken from the "NHLBI Fact Book, 1993" and is derived from a 1980-based table developed by Dorothy Rice et al (HCFA Review, 1984).

COSTS ASSOCIATED WITH RECOMMENDED THERAPIES

Question. NIH often convenes consensus conferences and other groupings of research experts to recommend specific treatments, screenings, or diagnostic procedures. Some of these NIH-endorsed recommendations would have a measurable fiscal impact (e.g., if screening for a particular cancer is recommended every two years, instead of once every three years, etc.) if adopted uniformly. Has NIH considered publishing estimates of the cost of adopting such recommendations whenever they are announced? Please discuss.

Answer. The NIH Consensus Development Program is the principal, but not the only, forum for reviewing and making public statements about the efficacy of emerging medical treatments and procedures. The Consensus Development Conferences are co-hosted by the NIH and its constituent Institutes, Centers and Divisions, and bring a non-government, independent panel to review the evidence on the emerging technology in question. The resulting Statement, issued by the independent panel

of experts, is not "NIH-endorsed" as implied by the question, yet this is easily inferred by the fact that the NIH prints and distributes the Statement broadly. Not all medical practice recommendations coming from the NIH are issued by the Consensus Development Program. Individual Institutes make recommendations, such as those made by the National Cancer Institute concerning breast cancer screening.

Consensus panels occasionally consider economic issues surrounding the technology under review, but they are seldom charged with making estimates of the fiscal impact of their recommendations. Cost issues are often discussed, but they do not carry the same weight as research results in arriving at a consensus of scientific judgment. Furthermore, it should be noted that the recommendations of the conference panel are not known in advance of the consensus building process. The Consensus Development Program considers the potential impact of each conference on a case-by-case basis. It does not routinely attempt to make estimates of the fiscal impact of its recommendations, as this falls outside our expertise and is seen to fall within the purview of the Agency for Health Care Policy and Research.

On two recent occasions such estimates have been made. A recent consensus panel commissioned a study of the cost savings from the use of antenatal steroids to prevent respiratory distress syndrome and related conditions in premature infants. The study was presented in the public session of the conference, held February 28 to March 2, 1994, and its merits and findings were discussed by the panel and the audience. In the consensus statement issued by the panel, it was estimated that the fiscal impact of following their recommendations would be approximately \$3,000 per treated neonate, or \$157 million per year if the rate of treatment were to rise from current levels (15 percent) to levels already practiced in some hospitals (60 percent). They viewed this assessment of cost savings as "conservative". A similar cost impact analysis has been made for the savings that would occur if ultrasound screening in normal pregnancies was not routine. This was commissioned as a follow-up to the RADIUS trial which indicated that such screening was not necessary. This trial was the result of a previous consensus conference.

SURVEY OF TYPES OF GRANTEES SUPPORTED BY NIH

Question. Last year, NIH published the results of a study it conducted in 1991 and 1992 to estimate the types of researchers supported in NIH research grants. The data series reported information in three-year increments, ending in 1990. Will the data on 1993 be published this spring? Will NIH report these figures on a prospective basis when it presents its budget request to the Congress next year?

Answer. There is no current effort to update this study which was based on a five percent random sample of RO1 and PO1 grants.

GRANTEE SALARY COSTS FUNDED BY NIH

Question. Unlike NSF, NIH does not seem to have a policy requiring university grantees to pay a minimum portion of the salaries of their professors, instead allowing grantees to charge 100 percent of their salaries to NIH grants. Do universities have some minimum amount of responsibility for supporting the researchers they employ? What sort of range might such a minimum contribution fall within? Why does NIH's policy continue to vary from NSF's?

Answer. The NIH policy authorizes the use of grant funds for salary of university grantees commensurate with the percentage of time actually devoted to the NIH-funded research project. The salary requested must be reasonable and conform to university policy and no portion of the investigator's effort on behalf of the university, e.g., teaching, administration, or clinical care, may be charged since it does not directly relate to the research project. Current NIH policy does not specify a minimum effort that universities must support. However, NIH grantees are currently subject to a legislatively imposed salary cap of \$125,000 per annum. Unlike the NSF practice which routinely limits the provision of grant funds to summer salary or instances in which there is a need for special release time, the NIH supports legitimate faculty research effort throughout the academic or calendar period. NIH believes there should be a serious examination of the responsibilities for faculty salaries. However, this is a complex issue which requires a great deal of study and consultation with the community.

SCIENTIFIC OBJECTIVES OF ORMH AND ORWH

Question. What are the scientific (e.g., non-training) objectives to which the funding for the Office of Research on Women's Health is applied? What are the scientific objectives to which the funding for the Office of Research on Minority Health is ap-

plied? How does the fiscal year 1995 request reflect an attempt to accomplish these objectives?

Answer. The Office of Research on Women's Health [ORWH] was established in 1990 and mandated by Congress in 1993 to redress inequities in women's health research. The primary scientific objectives are to acquire data on the normal biological processes as well as diseases, disorders, and conditions that affect women of all socioeconomic and racial and ethnic groups, across their life span. Working in close cooperation with the Institutes, Centers, and Divisions [ICD's] of the National Institutes of Health [NIH] and with the scientific and advocacy communities, ORWH has established a women's health research agenda.

This scientific agenda underscores a commitment to research across the biomedical research spectrum from molecular biology to clinical trials. The ORWH research agenda emphasizes not only those diseases that are the leading cause of morbidity and mortality in women, such as cardiovascular diseases and malignancies, but also diseases that affect far fewer women, but may have equally devastating consequences, e.g., lupus erythematosus, Sjögren's syndrome, temporomandibular joint disorders, endometriosis, and eating disorders. The research agenda continues to be refined as new scientific information evolves and dictates continuing or modified investigative priorities.

The fiscal year 1995 ORWH request has been for funds to continue to implement the comprehensive agenda set forth in 1991 but with revised or additional priorities as indicated by scientific developments. While ORWH continues its broad base of funding for diverse investigations, the fiscal year 1995 request concentrates on intensive efforts in specific areas. These are areas that have been generally understudied in the past, requiring initiation of substantive inquiry. They include women's urological health, autoimmune diseases, aging processes, reproductive health, including menopause and its health consequences, sexually transmitted diseases, occupationally-induced diseases and disabilities, and the effects of violence.

The fiscal year 1995 request will also be used to fully implement and monitor the guidelines on the inclusion of women and minorities in clinical research as was legislatively mandated in the NIH Revitalization Act of 1993. ORWH funds will be utilized to assist in ensuring that such inclusion of women does occur across the full biomedical human subject research spectrum.

The scientific objectives of the Office of Research on Minority Health [ORMH] are based on the recommendations of the NIH Minority Programs Fact-Finding Team, which was charged with assessing NIH programs and making recommendations to increase attention to minority health research issues and to enhance the numbers of minority biomedical scientists. The Fact Finding Team recommended that research programs be focused in three key areas: Life-Span Issues, Chronic Diseases, and Infectious Diseases.

Life-Span issues related to extending the lives of minorities and lowering morbidity throughout the lifespan include prenatal and infant concerns, childhood and adolescent concerns, and adult concerns up through the elder years. Chronic diseases with high incidence among minorities include coronary heart disease, high blood pressure and stroke, asthma, cancer (especially breast, lung, and liver cancer), renal disease, diabetes (and the relationship of obesity to diabetes), and alcohol-related diseases such as cirrhosis. Infectious diseases with a high incidence among certain minority groups include sexually transmitted diseases, viral hepatitis, tuberculosis and bacterial meningitis. The Fact-Finding Team also emphasized that the escalating impact of AIDS on minority populations also requires immediate and urgent attention.

The centerpiece of the ORMH activities is the Minority Health Initiative, whose components respond to the recommendations of the Fact-Finding Team. The Infant Mortality component of the Minority Health Initiative supports community-based epidemiological and clinical research to address the problem of the unacceptably high infant mortality rate in Washington, D.C. In fiscal year 1995 the ORMH has requested \$5 million to continue this research.

An additional component of the Minority Health Initiative focuses on children's health, including injury-related morbidity, lead poisoning, asthma, learning disorders and hearing and speech impairments. The ORMH has requested \$7 million to continue research in these areas in fiscal year 1995.

The Youth Behavior Initiative focuses on evaluating and comparing various community-based interventions for decreasing violence-related injuries and deaths, sexually transmitted diseases, and unintended pregnancies in minority youth ages 10-24. It is requested that this component be funded at \$5 million in fiscal year 1995.

The Minority Health Initiative includes a variety of research projects, both intramural and extramural, related to the health problems of young adults. This component supports research on AIDS, glaucoma, tuberculosis, hypertension and other

diseases impacting the quality and longevity of life of minority adults. The ORMH has requested \$5.502 million to fund these initiatives in fiscal year 1995.

The aging component of the Minority Health Initiative funds research centers for the study of diseases and conditions that lead to ill health and disability in older minority populations, such as hypertension, cancer, diabetes, and arthritis. It is requested that this component be funded at \$2 million in fiscal year 1995.

The fiscal year 1995 budget request closely parallels the scientific objectives delineated by the Fact-Finding Team. The health components of the Minority Health Initiative address life-span issues, as well as the chronic and infectious diseases that disproportionately affect minority groups during each stage of life.

SENIOR BIOMEDICAL RESEARCH SERVICE

Question. The Federal Employees Pay Comparability Act of 1990 authorized the Public Health Service to create a Senior Biomedical Research Service. I understand that this authority has not yet been implemented. What is the delay? Is this authority not required? Have the senior scientists at NIH attracted in the past 3 years been lower-quality than those you might hope to attract if the SBRs were implemented? If not, is the authority necessary? Has NIH been revitalized to the point that use of this authority is no longer the priority it once was?

Answer. Implementation of the SBRs has been deferred because final regulations have not been approved. The NIH has recently forwarded a proposal to the Public Health Service. Areas to be resolved involve pay setting and the distribution and use of SBRs slots for recruitment versus retention.

The SBRs may be a very useful and viable alternative personnel system for the NIH because it provides for benefits not available under current personnel systems. Over the past 3 years, NIH was successful in filling with outside appointments only five intramural research positions in the Senior Executive Service, out of a total of 22 that were advertised (two others were filled with internal promotions). These are positions that are equivalent to Full Professors or Department Chairs in research intensive universities. We believe that the Senior Executive Service often does not offer the flexibility necessary to fill research positions at these levels.

Our view is that the SBRs would be used to recruit scientists at several levels, from the equivalent of Associate Professor to Department Chair in major research intensive universities. The system would offer great career opportunities for scientists at the Associate Professor level, and higher incentives in the recruitment of senior scientists.

REVIEW OF THE FINANCIAL MANAGEMENT PLAN

Question. The Congressional Justification for the fiscal year 1995 Budget Request mentions that NIH is considering modifying the Financial Management Plan. When does NIH plan to present its modifications to Congress?

Answer. The initial NIH Financial Management Plan [FMP] was developed in fiscal year 1991 to articulate a strategic plan for meeting the challenges of operating within limited federal resources while providing an environment in which the current unprecedented pace of advances in biomedical knowledge can be maintained. The fiscal strategies developed in the FMP have been in effect since fiscal year 1992. These strategies have succeeded in reducing the rate of growth in average costs for competing grants over the last three years while providing stability and predictability of support for scientists during the course of their committed research support. However, it is clear that the FMP was formulated in response to a specific set of fiscal conditions existing at a particular time.

In fiscal year 1994, with several years of experience and the encouragement of Congress, NIH began the process of modifying the FMP to develop more broadly applicable principles of financial management. The goal for these modifications is to develop a set of financial management principles that will be applicable over the long term, regardless of appropriation levels for individual Institutes and Centers [IC's]. In revising the FMP, the NIH intends to continue to provide the funding stability necessary to maintain momentum in biomedical research advances and, by supporting the most highly meritorious new initiatives, to accelerate progress in biomedical research. These goals are fundamental to the credibility of the FMP with the scientific community and Congress. Within the research projects grant [RPG] portfolio, stability translates into ensuring that grants will be supported throughout the life of the award at committed levels, and that new and competing continuation research projects will be supported at levels appropriate to funding the most promising research within available funds.

NIH has begun the review of current FMP and is in the process of identifying the issues and developing the comprehensive analyses that are needed to update the Plan.

INCREASES FOR THE NIH AND ITS ICD'S

Question. Continuing the trend from past years, the percentage increase for NIH as a whole exceeds the request for the NIH Institutes. If the point is to increase our investments in the Institutes, this is worrisome. Please display the percentage increase for NIH appropriations in each of the past 5 years, showing the average percentage increase for the total of the Institutes, Centers, and Divisions versus the total percentage increase for NIH as a whole. Please discuss why the increases seem to favor something other than the Institutes, and how long this approach can continue.

Answer. The following table displays the appropriation for each Institute, Center and Division [ICD's] within the NIH for the past five years. The table also reflects a column showing the percent change between consecutive years.

Although there is some variance in the change among the individual appropriations the greatest change is within the Office of the Director appropriation. From this display, it appears that the ICD's are not receiving the funds as intended for research programs, however this is not the case. During the past five years, the NIH has supported several high priority initiatives that cut across all of the ICD's. Since we are not able to determine the amount to be allocated to each ICD at the time of the appropriation the funds are appropriated to the Office of the Director and later distributed to the Institutes based on the ICD's involvement with the program. Programs such as the Minority Health Initiative and the Women's Health Initiative fall within this category. For example, in fiscal year 1993 and fiscal year 1994 approximately 70 percent of the funds appropriated to the Office of the Director were later allocated to the ICD's.

In addition, a large portion of the increase received by the ICD's in the past five years has been targeted for specific programs, i.e., Breast Cancer Research (primarily supported by NCI) and High Performance Computing Research (primarily supported by NLM). These are high priority areas and should receive support.

The following table displays the appropriation for each of the NIH Institutes, Centers and Divisions as well as the sum of these appropriations—total NIH—for each of the last five years. A column is also provided to show the percentage change in appropriations between consecutive years. Although there is some variance in percent change among the individual NIH appropriations, I want to assure you that the data shown for the total NIH is an accurate composite of the individual appropriations.

NIH APPROPRIATIONS FISCAL YEARS 1991-95

[Dollars in thousands]

	Fiscal year 1991	Percent change 1992-91	Fiscal year 1992	Percent change 1993-92	Fiscal year 1993	Percent change 1994-93	Fiscal year 1994	Percent change 1995-94	Fiscal year 1995
National Cancer Institute	\$1,714,784	14.5	\$1,962,587	0.8	\$1,978,420	5.0	\$2,076,382	5.5	\$2,190,421
National Heart, Lung, and Blood Institute	1,126,942	5.5	1,188,593	2.2	1,214,740	5.2	1,277,880	3.7	1,324,871
National Institute of Dental Research	148,918	6.4	158,417	1.7	161,142	5.2	169,520	3.7	175,873
National Institute of Diabetes and Digestive and Kidney Diseases	615,272	7.1	658,925	3.3	680,672	5.2	716,054	3.7	742,547
National Institute of Neurological Disorders and Stroke	541,743	6.7	577,938	3.7	599,488	5.2	630,650	3.7	653,734
National Institute of Allergy and Infectious Diseases	906,251	5.8	959,082	2.6	984,227	8.1	1,063,704	5.4	1,120,973
National Institute of General Medical Sciences	760,010	7.5	816,844	1.9	832,235	5.2	875,511	3.7	907,598
National Institute of Child Health and Human Development	478,956	8.2	518,251	1.8	527,767	5.1	554,881	4.7	580,891
National Eye Institute	253,241	6.2	268,978	2.6	275,917	5.2	290,260	3.7	300,892
National Institute of Environmental Health Sciences	241,028	3.1	248,575	1.1	251,187	5.2	264,249	3.6	273,858
National Institute on Aging	323,752	18.4	383,382	4.2	399,531	5.2	420,303	3.6	435,424
National Institute of Arthritis and Musculoskeletal and Skin Diseases	193,247	5.1	203,047	4.5	212,247	5.2	223,204	3.7	231,371
National Institute on Deafness and Other Communication Disorders	134,935	10.3	148,789	4.0	154,776	5.2	162,823	3.6	168,689
National Institute of Mental Health	511,967	9.5	560,504	4.0	583,142	5.2	613,444	4.0	637,927
National Institute on Alcoholism and Alcohol Abuse	383,656	4.0	399,151	1.3	404,183	5.2	425,201	4.3	443,696
National Institute on Drug Abuse	158,141	8.6	171,748	2.7	176,446	5.2	185,617	3.7	192,498
National Institute of Nursing Research	39,722	13.1	44,929	7.9	48,496	5.2	51,018	3.9	53,028
National Institute of Research Resources	335,255	(6.3)	314,213	(5)	312,657	6.2	331,915	5.9	351,354
National Center for Research Resources	87,418	19.8	104,762	1.3	106,134	19.8	127,112	19.6	152,010
National Center for Human Genome Research	17,519	11.8	19,593	.6	19,715	10.0	21,677	6.6	23,102
Fogarty International Center	8,972,757	8.2	9,708,308	2.2	9,923,122	5.6	10,481,405	4.6	10,960,757
Subtotal	91,408	8.4	99,088	4.6	103,613	13.9	118,019	17.4	138,521
National Library of Medicine	99,951	44.2	144,154	31.9	190,138	19.5	227,190	14.5	260,183
Office of the Director	176,845	(38.5)	108,840	(1)	108,731	2.1	111,039	2.3	113,539
B&F									(1,379,052)
Office of AIDS Research									
Total, NIH	9,340,961	7.7	10,060,390	2.6	10,325,604	5.9	10,937,653	4.9	11,473,000

Note: The fiscal year 1995 Budget Request includes all AIDS funds in the OAR. However, for comparability, AIDS monies are shown in the respective ICD's.

QUESTIONS SUBMITTED BY SENATOR HATFIELD

RARE DISEASE RESEARCH

Dr. Varmus, as you know, I have introduced legislation in the Senate, S. 1203, to establish a Center for Rare Disease Research at the NIH. This effort is designed to strengthen the Office of Rare Disease Research which already exists within your own Office. I am hopeful that through this effort, we will be able to better stimulate and enhance the coordination of rare disease research. My legislation calls for two major focuses for the Center—a Strategic Research Plan and a National Rare Disease Clinical and Informational Database. I am pleased to learn that you are already moving toward the latter.

Answer. I received a letter last week from a young woman in Indiana who has Ectrodactyly-Ectodermal Dysplasia-Clefting Syndrome [EEC]. She wrote to me about her condition and told me that currently no doctor knows "what is wrong or why it is happening. One doctor familiar with EEC said he has never heard of the problems I am experiencing." She went on to note that rare disease research offers the one remaining hope she has for treatment—without it, "I have no hope," she told me. She is not alone in her trial—through my sponsorship of this legislation, I hear frequent tales of such pain. We must move beyond the piecemeal, ad-hoc approach we currently have to rare disease research.

Question. I would like to hear your views on formulating a strategic research plan for rare diseases and/or convening a national consensus conference in this area which could highlight the scientific opportunities and the obstacles to better understand and treat rare disorders.

Answer. It has been over five years since the National Commission on Orphan Diseases submitted its report to Congress. This report contained several recommendations to stimulate research and development of orphan products for rare diseases or conditions. Many of these recommendations have been implemented or are under development, for example, the Rare Disease Research Database and Monitoring System. This may be an appropriate time to re-visit the rare disease research and orphan products development issues.

Since, by definition a Consensus Development Conference has certain requirements, it may be that another forum may be more appropriate to examine the many cross-cutting issues and needs of, not only the rare disease research community, but the entire population exposed to rare diseases, including physicians and patients with rare diseases or their families. Dialog would assist in determining the need for and direction of a strategic plan for research and development of orphan products. The NIH would welcome sponsors from both the private and Federal sectors.

Since there are an estimated 5,000–6,000 acquired or genetic rare diseases, developing and implementing a strategic plan to support research on all of these diseases may be a difficult and extremely costly task. The NIH continues to identify research opportunities for the diagnosis, prevention, and treatment of the rare diseases and the obstacles to orphan products research and development. Areas of discussion would also include methods to increase the awareness of physicians, other health care professionals and the general public to the availability of information on rare diseases and conditions.

NIH, through its intramural and extramural research programs, supports research on between 700 and 900 rare diseases at any point in time. In 1993, the NIH reported research advances on over 180 rare diseases to the DHHS Orphan Products Board.

You mentioned the needs of a particular patient with ectodermal dysplasias. The Office of Rare Diseases Research and the National Institute of Dental Research [NIDR] has had a close working relationship with the National Foundation for Ectodermal Dysplasias, and its Executive Director, Mrs. Mary Kaye Richter. I suggest your constituent contact Mrs. Richter at 618–566–2020 for additional information. Mrs. Richter has been a leading proponent articulating the need to establish an information source for patients, such as your constituent.

The NIDR has been a willing partner in the recently created National Alliance for Oral Health, a consortium of professional dental and health voluntary organizations committed to improving research, education and care for patients with systemic diseases or handicapping conditions. These conditions include ectodermal dysplasias, Sjögren's syndrome, craniofacial birth defects, cleft lip and palate, and chronic pain that compromise oral health.

The activities of this Alliance led to the establishment of the National Oral Health Information Clearinghouse. With the encouragement of Congress and private sector organizations, NIDR is supporting the clearinghouse to serve public and professional needs for information on oral health and disease. The Clearinghouse is operational

and can be reached at 301-402-7364. The activities surrounding the development of this information clearinghouse are indicative of the cooperative working relationships the NIH has established with many of the rare disease voluntary health organizations. I anticipate a heightened awareness of the special needs of the rare disease research and patient communities as the activities of the NIH continue through the efforts of the Institutes, Centers, and Divisions [ICD's] and the Office of Rare Disease Research.

AD HOC PANEL FOR HUMAN EMBRYO RESEARCH

Dr. Varmus, I understand that at present there is no standing board to consider ethical issues which arise from research conducted and/or supported by the NIH. The Department has elected not to re-establish the ethics advisory board. Thus, most of what has been done on ethical issues and research is done on an ad hoc basis. For example, I understand, that Dr. Alexander, Director of the National Institute of Child Health and Human Development, recently took the initiative to establish an ad hoc panel to examine human embryo research.

Question. Dr. Varmus, is it your view that this ad hoc approach is preferable to a standing board?

Answer. I think there are advantages to each approach. The NIH has used ad hoc advisory panels several times in the last five years on a wide range of issues. In most instances, these panels were formed as subcommittees to a standing advisory committee, the Advisory Committee to the Director, NIH. Currently, the NIH Human Embryo Research Panel is assisting us in considering the ethical implications of research involving the ex utero human embryo and the development of guidelines for Federal funding of such research.

The ad hoc approach is flexible and can be employed as the need arises. The mandate of an ad hoc panel is focused and manageable, and its membership can be tailored to ensure that the most relevant scientific, ethical, legal, and societal expertise is represented. The NIH has received sound advice from ad hoc panels and been well served by them. As the ethical, legal, and social implications of innovations in medicine and research continue to present public policy dilemmas for the Nation, we may need to consider other mechanisms and approaches to address such challenges, including the possibility of establishing a standing Ethics Advisory Board.

NIH INTERFACE WITH THE BIOETHICS COMMISSION

Question. How do you anticipate the NIH interfacing with the Bioethics Commission which some of us in the Congress have been working on with Dr. Gibbons?

Answer. Although it would serve at a transgovernmental level and address global issues common to more than one agency, the mission and functions of the Bioethics Commission would be highly relevant and important to the NIH. The NIH would interface with the Commission by providing information on research programs and agency policies and sharing advice and perspectives on any pertinent issues under review. NIH would fully support the work of such a Commission.

RECRUITMENT OF DIRECTOR FOR NATIONAL CENTER FOR SLEEP DISORDERS

I want to thank you, Dr. Varmus and Dr. Lenfant, for your support in approving the charter of the National Center for Sleep Research, and for both appointing the advisory committee, and assigning the initial staff. It is my hope that the NIH will do what it takes to expeditiously recruit and appoint a senior level scientist as the Director of the Center.

Question. Can you estimate when that appointment will be made?

Answer. The Institute has requested approval to recruit a Director at the Senior Executive Service [SES] level in order to attract the best candidates possible, and the NIH has been directed to reduce the number of SES as well as positions at the GS-14 and GS-15 levels. For these reasons, it is not possible to predict a definite date when the appointment will be made.

RECRUITMENT OF DIRECTOR OF NINDS

Question. Dr. Varmus, has the new Director of the National Institutes of Neurological Disorders and Stroke been selected? If not, can you estimate for us when that selection will be made? I would appreciate being informed of that choice as soon as possible.

Answer. We are currently considering a list of candidates referred by the search committee. One individual has emerged as the leading candidate, and we are in the process of discussing the position with that person. We hope to be able to finish the

recruitment and nominate a candidate for the position in the next several weeks. Because this position reports to the Director, NIH, the appointment is subject to the approval of the Assistant Secretary for Health. We will be happy to inform you of the choice as soon as possible.

LATEST TREATMENT FOR PARKINSON'S DISEASE

Dr. Varmus, in our report language, we asked for a report identifying potential treatment options and a plan for developing a coordinate research agenda for Parkinson's Disease.

Question. What do you see on the horizon in the way of promising treatments? *Answer.* At the present time, the most effective treatment for Parkinson's Disease [PD] is still the drug L-dopa which has been in general use for some 20-25 years. There are a number of problems including loss of effectiveness and troublesome side effects which follow the extended (10 years or more) use of L-dopa. Most research into new treatment modalities have focused on alternatives to L-dopa for those patients who are unresponsive to it or for whom its effectiveness has diminished. We are encouraged by the fact that investigators report many good leads with high promise. NINDS-supported research on Parkinson's Disease proceeds along several broad fronts: finding the cause(s) of the disorder, developing new drug therapies and optimizing therapy with current medications, new methods for drug delivery, tissue implants and other surgical treatments.

Several investigations of causes, such as environmental and endogenous toxins, genetic predisposition, and altered motor circuitry and neurochemistry are being supported. New epidemiological studies have recently been initiated to identify risk factors for this disorder.

The search for better therapeutic interventions continues. Animal models are being used to study the pathophysiology of the disease and develop novel therapies. Clinical studies on ways of improving levodopa therapy, including use of ancillary drugs, offer the most immediate promise for an improved quality of life for many Parkinson's Disease patients. NINDS intramural scientists are working to develop a dopamine agonist that will target the specific dopamine receptors involved in Parkinson's Disease, avoiding the receptors involved in the negative side effects now experienced by nearly half of the patients receiving levodopa. Work is continuing to determine if deprenyl and other antioxidants reduce or neutralize toxins and actually prevent brain cell destruction, to determine longer term effects of these compounds, and to explore the efficacy of other drugs to treat Parkinson's Disease.

NINDS intramural scientists showed in a small trial this past year that a new drug (Ro 40-7592) blocks the breakdown of dopamine and levodopa, and prolongs relief of symptoms by more than 60 percent when added to standard treatment. This helps patients avoid the "wearing-off effect" while taking fewer doses and smaller amounts of the standard levodopa/carbidopa medication. NINDS intramural and grant-supported scientists are beginning to understand the factors involved in the specific nerve cell degeneration involved in Parkinson's Disease; these include glutamate excess in over-stimulating the NMDA receptor and the action of free radicals. They are encouraged that stimulating trophic factors can help in the repair of the dopamine-producing nerve cells that are not yet destroyed, but are weakened, by the effects of Parkinson's Disease.

A major clinical trial began this fiscal year to study the efficacy of transplanting fetal tissue into patients with advanced PD. Research on other surgical approaches, such as focally placed lesions in the motor circuitry of the brain, will also be supported. The NINDS supports experimental methods, such as alternative tissues for implantation, growth factors, and genetically engineered cells, that may someday preclude the need to use human fetal brain tissue or the patient's own adrenal tissue. Genetically engineered connective tissue cells and dopamine-producing cells encased in polymer beads are examples of such approaches to treatment. Other avenues include attempts to grow human fetal tissue in culture to provide larger quantities of functional implantable tissue.

COORDINATION OF PARKINSON'S DISEASE RESEARCH AT NIH

Question. What steps are being taken to better coordinate Parkinson's research among the various Institutes?

Answer. In response to the report language on this topic, NINDS surveyed the NIH ICD's to identify research activities related to Parkinson's Disease. The report documents a robust program of research directed at or relating to Parkinson's Disease, totalling \$71.9 million for NIH in fiscal year 1993. Major participants include NINDS, as the lead institute for this major neurological disorder; the National Institute on Aging, with interest in Parkinson's as a disorder with higher incidence in

the aging population; the National Institute of Mental Health, focusing on neurobiological and behavioral aspects; and the National Institute of Environmental Health Sciences, which supports research investigating possible environmental influences on Parkinson's Disease. Other ICD's have a research interest in the biology of the brain which has relevance to Parkinson's Disease—for example, the study of neurotransmitters, receptors, and tissue implants.

The report concluded that longstanding NIH research management practices are adequate to ensure the Institutes' coordination of Parkinson's Disease research. These include the guidelines for assignment of incoming applications to the appropriate review group and funding unit; requirements that all program solicitations be circulated for review, comment, and possible cosponsorship prior to publication; and opportunities for intramural collaborations.

QUESTIONS SUBMITTED BY SENATOR BOND

EFFECTS OF INDIRECT COST PAUSE

The President's budget proposes a "pause" in funding for indirect costs by freezing these payments at the fiscal year 1994 level for one year. I am concerned about the effect this will have on research programs and the effect it will have particularly at the very successful research institutions who are penalized the most under this proposal.

Question. Why is this freeze needed and has NIH looked at what real effect this might have on successful research programs?

Answer. The Administration has proposed the pause so that the Office of Management and Budget, the Office of Science and Technology Policy, and the Council of Economic Advisors can address the underlying problems in a constructive fashion with advice from affected Federal research agencies and representative institutions. This examination will take place in 1995 while we "pause" from any other changes in policy or indirect costs reimbursements.

REVIEW OF INDIRECT COSTS

Question. What expenses that are currently allowed as indirect costs are contemplated for disallowance under a thorough review and renegotiation with research universities?

Answer. OMB has not begun its assessment, and we think that it is premature to speculate as to outcome at this time.

NATIONAL CANCER INSTITUTE

STATEMENT OF SAMUEL BRODER, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Let us get the rest of the directors up here.

What I would like to do is just to ask that any prepared statements be submitted for the record in their entirety. I appreciate your being here. I think it is important to get you all together here around this table, at least once a year so I can eyeball you and know exactly who you are and so perhaps you can understand from us the direction in which we are headed.

I am sorry that Senator Mack had to leave again. He has been a very valuable member of this subcommittee. What I might do is just ask a couple of questions, and if I could just go down the different Institutes, if you could just answer those. And I might come back with some follow-up questions that are specific to a few of the Institutes.

The two questions I have are: One, if your budget were increased by 50 percent over the next 5 years, what impact would that have on your Institute, your center? What could you do with that type of an increase if you could actually see it coming over the next 3, 4 years, next 4 years?

And be as specific as possible in terms of improved success rates, new grants, areas of research that you could get into that you may not be able to now.

And the second question would be to detail the impact on your Institute of the President's Executive order reducing the FTE's over the next 5 years. What would be the impact on your intramural program, on research management and support? I think that is important for the record to hear from each Institute director on those two aspects.

I do not want to limit you to that, however. If you have other things that you think it would be important for me to know and to get on the record for this subcommittee, please feel free to do so. And why don't I just start with the Institutes as I have them listed here, and if you could respond to those two, you might do that very briefly. And if you have something else that you specifically want us to know, please delineate that.

SUMMARY STATEMENT OF DR. SAMUEL BRODER

I will start with Dr. Broder, the Director of the National Cancer Institute. Good to see you back again.

Dr. BRODER. Thank you, Mr. Chairman. It is a pleasure to be here. I will respond to your two questions.

One would be what would we do with an increase in the current budget to a level of a 50-percent increase. We would be in an un-

usual opportunity to support and promote increased basic research, the kind of investigator-initiated research in which the genius of the investigators throughout this country could be tapped to develop new ideas in ways that a central governmental authority cannot dictate. I think that is one of the real strengths of American science.

Without appearing to convey any chauvinism, I feel American science is the best there is, and it did not only happen by accident. It happened by a long-term commitment made over many decades to develop a system of investigator-initiated research, where anyone can send in an application and stand before a peer group without having to go through a more senior level person or ask a higher level structure for permission, and so on.

I think this system permits novel approaches and it permits the kind of creative insights and it permits those who dissent from orthodoxy to have their day and to sometimes prevail.

I attended, as did others at this table, a memorial for Dr. Howard Temin, who is a classical example of someone who in one era was considered to be at the fringes of things, at least in some quarters, and then he was vindicated and validated in his pursuit of what ultimately turned out to be a new class of retroviruses and a special concept of how genetic information flows in a reverse direction, from RNA to DNA, not then thought to be possible.

So I believe we would be able to support a substantial increase in that kind of creative effort were we to reach the budget levels that you are describing. We would be able to fund approximately 2,700 research grants, with a success rate that would approach 60 percent. That would be our first priority. That would tap into the inherent genius of the American scientific system.

But at the same time, we would attempt to support a number of activities that would help us try to translate observations that are made at the lab to the bedside and to the clinic. We would have very strong programs that would help us adapt some of the very exciting results that you heard today, of which one would be the colon cancer gene. But we expect that kind of activity to be duplicated in multiple arenas.

We expect important advances in BRCA-1, which is a gene that encodes for certain forms of familial breast cancer and ovarian cancer and, ironically, possibly even prostate cancer in some settings. So we would be very anxious to develop a system on a community-based level to develop counseling, to develop translational information, to get the translation of those types of activities, and that would be an extremely high priority.

We would also support our clinical trials approaches, where we have organized appropriately controlled clinical trials where we can make definitive answers to many of the questions that sometimes can go unresolved for decades or more, and I think all of those types of activities are important.

We would also want to make sure that the science that we generated reached underserved groups, reached rural populations, reached African-American populations, reached out to Hispanic populations, and so on, because we believe that at the NIH we can, paradoxically, be an engine that drives disparity.

We have seen that in certain forms of cancer, for example, in colon cancer, where the death rate for white-Americans is actually falling, whereas the death rate for African-Americans is actually going up, particularly under the age of 65. We actually believe, in a counter-intuitive way, that the technologies that we generate may drive inequities in society if they are not equally applied, if there is not an even diffusion, if you will, if all who have need do not find a way of gaining access.

So in that sense, our science agenda is part of the health care reform agenda, if you want to look at it that way, and we think that is a very important issue and we would use some of the increase that you are describing exactly for those purposes.

PREPARED STATEMENT

We would try to strengthen our women's health initiatives and all of the other issues that you mentioned, and particularly to have strong community-based clinical trial activity. We would also try to have very strong programs in environmental carcinogenesis and in occupational cancers and related issues, to supplement the very large agricultural study which we have initiated, in which over 100,000 farmers and their families will be studied.

It is ironic that the State of Iowa is one of the centers for that. Your chairmanship had nothing to do with that.

Senator HARKIN. I hope not.

Dr. BRODER. It did not. We did this on the basis of peer review, and Iowa and North Carolina will be focal points for learning what the environment may do, what occupational exposures to pesticides and other things may have, and how they may interact with the human genes and so on, that may allow us to predict what kinds of exposures may yield what kind of diseases.

So those types of activities would be extended.

[The statement follows:]

STATEMENT OF DR. SAMUEL BRODER

This is a time of significant progress in cancer research, but it is also a time of considerable challenge. A number of cancers are on the rise, notably breast, prostate, and lung cancers. NCI foundation stones of basic cancer research, clinical trials, and a nationwide network of cancer centers provide the optimal basis for the new discoveries needed to improve cancer prevention and cancer care in the community. Translation of advances into clinical practice is speeded by the NCI Specialized Programs of Research Excellence [SPORC's] in breast, prostate, lung and, most recently, gastrointestinal cancers. Diffusion of research results to the public and the professional and research communities is carried out through the Cancer Information Service, PDQ, CANCERFAX, Cancer Net and the Journal of the National Cancer Institute.

A number of genes involved in specific cancers have been isolated. For instance, a gene named MSH2, involved in as many as 1 in 6 colon cancers, was identified this year. This gene also appears to be involved in a number of other cancers as well. Each new genetic discovery guides the development of specific diagnostic approaches, interventions, and treatments. For instance, an experimental blood test has been developed for another genetic mutation that predisposes individuals to a rare, inherited type of colon cancer, known as familial adenomatous polyposis [FAP]. As there is increasing ability to detect very small tumors and to identify rapidly growing tumors, there will be increasing ability to treat appropriately and to reduce cancer mortality.

Today, nearly 70 gene therapy protocols, using varied approaches, have been approved. Gene therapy techniques are being used experimentally to treat melanoma, kidney cancer, small cell and non-small cell lung cancer, ovarian and breast cancers,

neuroblastomas, glioblastomas, and various lymphomas and leukemias as well as immune disorders and cystic fibrosis.

This field of gene therapy provides an example of how cancer research progresses from over 20 years of research in genetics, immunology and biotechnology to safety and efficacy studies and then into clinical application. This field was so new that a new advisory structure had to be created. Finally, in August 1990, two little girls with a serious, genetically determined immune disorder were treated with gene therapy. They have continued to do well and are now attending school. This pilot study was the result of teamwork involving NCI and the National Heart, Lung and Blood Institute.

Throughout medical history, vaccines against bacteria and viruses have protected against deadly infectious diseases. There are similar hopes for cancer vaccines. A new vaccine combines the gene for carcinoembryonic antigen [CEA] with vaccinia virus. To date, 20 patients with gastrointestinal, breast or lung cancer have been inoculated with CEA-vaccinia vaccine. In another approach, p53, a mutated tumor suppressor protein, is used as a vaccine to stimulate killer T cells which attack the tumor.

NCI scientists are examining the effects of environmental and occupational exposures as well as the interaction between heredity and environment, including examination of issues of high public concern such as radon, electromagnetic fields, and cellular telephones.

Breast cancer rates in the Northeast and in the mid-Atlantic states are high, and several epidemiological studies are being planned to explore the reasons for these high rates. For example, the Long Island Breast Cancer Study Project is looking at the various factors contributing to breast cancer, including factors such as electromagnetic exposures, water, airplane exhaust, organic solvents, polychlorinated biphenyls [PCB] and polybrominated biphenyls [PBB], and pesticides which will be examined in conjunction with case-controlled studies of women in the community.

Because modern agricultural practice has relied heavily on chemicals, scientists are looking to see if this is related to high incidence rates of cancer in farmers. A major epidemiologic study is being carried out by NCI, the Environmental Protection Agency, and the National Institute of Environmental Health Sciences. About 100,000 farm workers and their families are being studied to determine the etiologic contributions of pesticides, chemicals, viruses, and other exposures.

Lung cancer and other tobacco-related cancers continue to end lives and devastate American families. NCI addresses these cancers through basic research on carcinogenesis as well as smoking control programs such as the American Stop Smoking Intervention Study [ASSIST] conducted with the American Cancer Society and state health departments. ASSIST will reach more than 91 million people in 17 states.

As part of a broad cancer prevention research program, NCI collaborates with the 5-A-Day for Better Health campaign to encourage the intake of more fruits and vegetables. Other programs focus on a specific audience and address many lifestyle factors. These include the National Black Leadership Initiative on Cancer, the National Hispanic Leadership Initiative on Cancer, and the Appalachian Leadership Initiative on Cancer.

The Prostate Cancer Prevention Trial and the Breast Cancer Prevention Trial, using finasteride and tamoxifen respectively as experimental agents, are both well under way. Both trials will include genetic analysis of biopsies to explore both inherited and acquired genetic mutations. Chemoprevention and bionutrition are becoming important cancer prevention strategies. Vitamin A-related agents, such as the retinoids and beta-carotene, have been shown to be effective in preventing second head and neck tumors.

Until simple tests are available to screen for molecular signs of cancer, NCI is stimulating research on new diagnostic tools. While conventional mammography definitively reduces mortality in women over age 50, the same benefit has not been demonstrated for younger women as a group. Thus, there is a serious need for new and better methods to detect early tumors in young women. Digital mammography methods may offer more accurate detection of breast cancer with better images, less radiation and the potential for electronic image transfer. Magnetic resonance imaging is being used to explore new ways of screening women for breast cancer.

A large screening clinical trial, the Prostate, Lung, Colorectal and Ovarian Cancer [PLCO] Trial, is assessing the predictive value of such tests as PSA, ultrasound, and CA125. About 37,000 men and 37,000 women will be enrolled with equal number as controls.

NCI scientists have contributed to the development of the majority of cancer drugs now approved by the FDA. Taxol, pentostatin, fludarabine, and deoxycoformycin have been approved within the last two years. Taxol is approved for ovarian cancer and is expected to be approved for breast cancer. Currently, Taxol

is being tested in various combination therapies. Research continues on analogues such as Taxotere and semi-synthetic and synthetic versions. More than 200 agents are in preclinical development.

NCI has made many contributions to AIDS research, including a recent finding that cell-mediated immunity is present in some individuals who have remained healthy despite exposure to HIV. This observation has implications for treatment as well as the development of an AIDS vaccine. Women are increasingly being infected with the virus and perinatal transmission to the infant is a very serious problem. One NCI study of twins suggests exposure in the birth canal is involved in transmission of the virus which points to possible use of an inexpensive viricidal solution to cleanse the birth canal to lower the risk of infection during delivery. From the onset of the AIDS pandemic, the NCI AIDS drug screen has been a national resource. To find promising agents against AIDS, NCI has tested more than 137,000 agents for anti-AIDS activity, including a number of natural products.

In conclusion, although there are important achievements in cancer research, there should be no illusions as to the challenge ahead. Cancer and AIDS present the most formidable challenges in science and medicine today. Mr. Chairman, the fiscal year 1995 Budget request for NCI is \$1,967,709,000. I appreciate the opportunity to testify before this Committee and will be pleased to answer any questions you might have.

BIOGRAPHICAL SKETCH OF SAMUEL BRODER, M.D.

Personal: Born February 24, 1945; U.S. citizenship; married, two children.

Education: University of Michigan, Ann Arbor, MI; 1966, B.S.—College of Literature, Science and the Arts (high honors); 1970, M.D.—School of Medicine (cum laude).

Employment: Stanford University, Palo Alto, CA, 1970–71, Internship (Medicine); 1971–72, Residency (Medicine). National Cancer Institute, National Institutes of Health, Bethesda, MD. 1972–75, Clinical Associate, Metabolism Branch; 1975–76, Investigator, Medicine Branch; 1976–81, Senior Investigator, Metabolism Branch; 1981–88, Associate Director, Clinical Oncology Program; 1989 to present, Director, National Cancer Institute.

Board certifications and licenses: 1973, Certified in Internal Medicine; 1977, Certified in Medical Oncology, Licensed to practice Medicine in California and Maryland.

Societies and organizations: American Society for Clinical Investigation (elected 1980); Association of American Physicians (elected 1989); American Federation for Clinical Research (Eastern Section Councilor); American Association for Cancer Research; American Society for Clinical Oncology; American Association of Immunologists; Clinical Immunology Society; Editor, Symposium on HTLV, September 1985, Cancer Research; Editor, AIDS: Modern Concepts and Therapeutic Challenges; Editor, Molecular Foundations of Oncology; Editorial Advisory Board for numerous journals; Fellow, American College of Physicians.

FTE REDUCTION

In terms of the question that you asked on FTE's—have I gone over my limit, time limit? OK. Well, in terms of the FTE issue, basically I would go over the limit in terms of trying to define the impact of that, because I believe that the current FTE situation will have a substantial effect on our ability to perform the science and administration that we need to do.

I can promise you that, irrespective of any FTE allocation, we will have excellent science and we will do our job and we will deliver what you expect. But we will have difficulty in terms of scientific recruitments and particularly providing the kinds of special career development opportunities that we think we should be dealing with.

Senator HARKIN. Do I know, Dr. Varmus, how many FTE's will come from each Institute?

Dr. VARMUS. Yes; we can provide you with those numbers readily. We have them here.

[The information follows:]

NATIONAL INSTITUTES OF HEALTH

[Full-time equivalents]

Total base-line	Fiscal year 1993			Fiscal year 1994		Fiscal year 1995		Total reduction from baseline (column 7-1)
	Target	Actual	Reduction from base-line (column 2-1)	Target	Reduction from 1993 target (column 5-2)	Target	Reduction from 1994 target (column 7-5)	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
17,448	17,128	17,105	- 320	16,804	- 324	16,393	- 411	- 1,055

Dr. BRODER. We will sustain approximately, rounding off, approximately a 10-percent loss in our FTE usage in the near future, and we will do so and we will try to continue to maintain excellence in scientific programs. But these are realities and there is no way that I can honestly tell you that that will not have an effect on our productivity and flexibility. So I view this as a serious issue and one that we will have to deal with. And we will accommodate it, but it is a reality.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Broder.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NATIONAL ACTION PLAN ON BREAST CANCER

Question. Included in the Administration's proposed NIH-wide \$84 million increase for breast cancer research is "at least \$10 million" to support implementation of the HHS Secretary's National Action Plan on Breast Cancer. Can you provide a summary of what's in that Action Plan, and how that \$10 million will be spent to implement the plan?

Answer. The Secretary's National Action Plan on Breast Cancer includes a broad array of initiatives to promote increased access and utilization of breast health services with improved coordination and information management among providers, patients and consumers. A variety of efforts will be undertaken to ensure the increased participation of underserved and at-risk populations in these initiatives and to establish public and private partnerships to further enhance breast cancer health education. Research efforts under the Action Plan address all aspects of breast cancer, including prevention, early detection, treatment and rehabilitation.

In furtherance of the Secretary's Plan, NCI will pursue the following collaborative breast cancer research projects with the Centers for Disease Control and Prevention [CDCP]: genetic and epidemiologic studies of breast cancer; outreach, training and counseling efforts for the public and at risk populations; patterns of care studies and cancer control surveys; environmental studies of pesticides and other chemical contaminants and their relationship to breast cancer risk; and the development of standard breast cytology criteria for a unified classification system.

1995 INCREASES FOR SELECTED AREAS OF RESEARCH

Question. It's my understanding that \$60.7 million of the increase for breast cancer is targeted for the National Cancer Institute. I also understand that the non-AIDS budget at NCI is proposed to increase by \$98.8 million overall (from \$1.86 billion to \$1.97 billion). According to my calculations, 61 percent of the increase in NCI's non-AIDS portfolio is targeted for breast cancer research.

What happens to the rest of cancer research at NCI? What levels of support do you propose to make for prostate cancer, ovarian cancer, etc.? Does this increase for breast cancer require you to cut other areas of cancer research to fit within your overall budget request?

Answer. In addition to breast cancer research, the 1995 budget request provides increases for a number of organ sites that exceed the overall Institute increase of 5.2 percent. Examples include cervical cancer which is slated to receive a 5.6 percent increase (\$2.5 million) for a total of \$47.5 million; ovarian cancer which will receive a \$3 million increase (up 8.7 percent) to \$37.8 million; and prostate cancer which is increasing by \$8 million or 14.6 percent to \$63 million. Leukemia research will receive an additional \$5.6 million, a 7.4 percent increase for a total of \$82 million and lymphoma research will increase by \$4 million or 8.4 percent to \$52 million.

Other areas of research will also receive increased funding but at less than the 5.2 percent overall increase for the NCI. These organ sites include bladder cancer, increasing by \$558,000 (or 3.4 percent) to \$17.2 million; colo-rectal cancer, increasing by 3.2 percent to \$84.6 million; liver cancer, increasing by 4.3 percent to \$41.9 million; lung cancer, with an increase of \$4 million or 4.1 percent to \$102.2 million; melanoma increasing 3.3 percent to \$32.8 million; pancreatic cancer increasing by 4 percent to \$12.3 million; skin cancer, up by 4.1 percent to \$61.4 million; testicular cancer which will receive a 2.8 percent increase to \$3.4 million; and thyroid cancer which increases by 4 percent to \$3.6 million.

BALANCED RESEARCH PROGRAM

Question. As money gets tighter and tighter, NIH budget requests appear to be directing more funds for specific areas of research.

How important is it to have a balanced research program that avoids disease specific research?

Answer. NCI is firmly committed to maintaining a balanced research program that emphasizes the importance of basic research as the underpinning of all future advances in cancer research. NCI allocates about one-half of its funds for basic research out of the conviction that the best answers to the prevention and treatment of cancer lie in a more effective understanding of the cancer cell and the process of carcinogenesis. Frequently, what is learned in basic research studies will have significant application to many disease areas. Today, cancer research at the basic cellular level is contributing to specific, often noninvasive, diagnostic tests and new individualized treatments for cancer, including gene therapy and innovative cancer vaccines.

While disease specific research has a prominent place in the Institute's portfolio, NCI continues to maintain a well-established and comprehensive research program in basic cancer biology, etiology, prevention, diagnosis, treatment and rehabilitation. In order to achieve this balanced approach to research activities, NCI supports investigator-initiated research project grants which address both basic research as well as disease targeted areas deemed to be of more major importance to the Nation's health care needs.

In addition, organ site specific research is conducted at NCI-supported Specialized Programs of Research Excellence (SPORE's), which provide an integrated setting for the conduct of basic research and its translation from the laboratory to the bedside. Currently, SPORE programs have been established to pursue breast, prostate, lung and more recently, gastrointestinal cancers.

Recognizing the importance of providing geographic access to state-of-the-art prevention and treatment, NCI supports a nation-wide network of Cancer Centers, Clinical Cooperative Groups and the Community Clinical Oncology Program.

Bolstering these efforts, NCI supports a significant array of outreach efforts through the Cancer Information Service [CIS], Physicians Data Query [PDQ], CANCERFAX, CancerNet, along with numerous initiatives that target minority and underserved groups.

Through cancer prevention and control activities, NCI continues to pursue a full spectrum of research, from basic through applied research, prevention clinical trials, and cancer surveillance.

In summary, NCI is committed to maintaining a proper balance among the various areas of NCI-supported research, including, but not limited to, disease specific research. In this way, NCI believes that fundamental and important scientific advances can be more readily achieved.

REDUCING THE RISK AND MORTALITY OF CANCER

Question. What is your progress to date in reducing the risk and mortality of cancer using the three methods specified in the NIH Revitalization Act Conference Report: large scale community intervention trials, community and physician education programs to encourage screening, and psychosocial interventions to improve the quality of life and increase treatment compliance? What projects have been funded with the setaside funds?

Answer. NCI is currently conducting a number of large-scale community intervention trials. These include the Breast Cancer Prevention Trial; the Prostate Cancer Prevention Trial; the Prostate-Lung-Colorectal-Ovarian [PLCO] trial; ASSIST; the Women's Health Initiative; the Carotenoid and Retinoid Efficacy Trial [CARET]; and Alpha-Tocopherol, Beta-Carotene [ATBC] Lung Cancer Prevention Study.

The Breast Cancer Prevention Trial tests the ability of tamoxifen, an antiestrogen, to prevent breast cancer in women at increased risk for developing this disease. Underway in the Community Clinical Oncology Program, the trials include 270 centers and 9,950 women.

The Prostate Cancer Prevention Trial tests the ability of the drug Proscar to prevent prostate cancer in men age 55 and older. Accrual to the trial began in October 1993 and includes 222 sites in the United States with 15,000 to 20,000 men. The PLCO study will determine the widespread use of screening tests for prostate, lung, colorectal, and ovarian cancers.

The American Stop Smoking Intervention Study [ASSIST] is a collaboration between the American Cancer Society, and State and local health departments in 17 States. The primary goal is to establish nonsmoking as the accepted community norm through a variety of targeted interventions.

The NIH Women's Health Initiative in which NCI participates will assess whether cardiovascular disease, cancer, and osteoporosis can be prevented by dietary, behavioral, and drug interventions. Three approaches will be studied: the effect of a low-fat diet on breast and colon cancers, and heart disease; the effect of hormonal replacement therapy; and the effect of calcium and vitamin D supplements on colon cancer and osteoporosis. Recruitment began in September 1993, with plans to include 60,000 postmenopausal women. Currently, awards have been made to one clinical center and coordinating center.

The Carotenoid and Retinoid Efficacy Trial [CARET] is a chemoprevention trial testing the combination of beta-carotene and retinyl palmitate on lung cancer. Two high risk populations include male and female smokers, and males with extensive exposure to asbestos. Currently, 17,315 people are enrolled in this study. Another Phase III trial is being conducted on 40,000 nurses, aged 45 and over, testing beta-carotene, vitamin E, and aspirin in preventing breast, lung, colon cancers, and heart disease.

The alpha-tocopherol, beta-carotene [ATBC] lung cancer prevention study is in collaboration with the National Public Health Institute of Finland to determine if these agents alone or in combination will prevent lung cancer among male cigarette smokers aged 50-59. Currently, 29,000 people have been randomized to placebo, single agent, or combined agents.

Two nutritional intervention trials were conducted in Linxian, China where the esophageal and gastric cancer mortality rates are among the highest in the world. There is suspicion that the population's chronic deficiencies of multiple nutrients are etiologically involved. In the general population trial, 29,584 adults ages 40 to 69 received a combination of daily supplements for five years. The half who took a supplement with beta-carotene, alpha-tocopherol, and selenium had a 13 percent decreased risk of dying from cancer and a 9 percent decreased risk of death from all causes. In the dysplasia trial, 3,318 persons with esophageal dysplasia (a precancerous condition) took either a multivitamin and beta-carotene and had an 8 percent lower risk of dying from esophageal/gastric cancer and a 38 percent lower risk of death from stroke. However, the small number of study participants leaves these results undecided. Because the Linxian population have chronic nutrient deficiencies and because there are not many types of cancer prevalent in this region of China, the results do not automatically translate to well nourished populations or to all cancers. Nevertheless, these studies suggest hopeful signs that vitamins and minerals may help to prevent the onset of cancers in healthy individuals.

NCI is conducting Community and physician education programs through the Community Clinical Oncology Program [CCOP]. CCOP is a major cancer control effort which links community-based physicians with clinical cooperative groups and cancer centers (as research bases) for participation in NCI research. Objectives of CCOP include implementing cancer prevention, control, and treatment clinical trials

research; testing intervention strategies; and assessing the impact of research on community practices.

In addition to these activities, NCI supports psychosocial interventions which include health care delivery, management of cancer pain, rehabilitation of adult cancer survivors, and the role of counseling. Health care delivery to cancer patients includes initiatives aimed at reducing the burden on family and community members who provide care for the cancer patient. Management of cancer pain involves acute care and hospice settings. The rehabilitation of adult cancer survivors strives to enhance the re-entry of cancer survivors into society. The role of counseling for cancer patients seeks to improve quality of life, including patients from culturally diverse backgrounds.

DIVISION OF CANCER PREVENTION AND CONTROL

Question. Please provide the Committee with a detailed accounting of funding for DCPC and how the division has used its funds for fiscal year 1992, fiscal year 1993, and fiscal year 1994. How were the extra funds provided pursuant to Public Law 103-43 used by DCPC?

Answer. In accordance with the NIH Revitalization Act, Cancer Prevention and Control activities increased to 7 percent of the total NCI budget in fiscal year 1994 for an increase of \$40,466,000. Below is a table which displays the allocation of the Cancer Prevention and Control budget for fiscal year 1992, fiscal year 1993 and fiscal year 1994 among its major program segments.

Some of the key initiatives underway due to the emphasis directed toward the Prevention and Control area include an expansion of chemoprevention research; continuing research on the interrelationships among hormones, bionutrition and cancer; development of intermediate endpoints (molecular and biological markers) to reliably quantitate individual cancer risk and to accurately evaluate effects of chemopreventive agents and other approaches to preventing cancer; studies of the application of research results among populations who suffer disproportionately from cancer, in particular the nation's minority communities; a portfolio of large-scale clinical studies of preventive regimens both chemoprevention and diet-based; patterns of care studies on prevention and control practices; and a 17-state study of community-based methods to prevent or reduce cigarette smoking [ASSIST]. Specific dollar increases for major program segments are as follows:

The Community Clinical Oncology Program [CCOP] received an increase for fiscal year 1994 of \$9 million directed toward prevention trials. The Breast Cancer Prevention Trial studies the role of tamoxifen in preventing breast cancer in women who are at increased risk for developing this disease. The Prostate Cancer Prevention Trial tests the ability of the drug Proscar to prevent prostate cancer and involves 15,000-20,000 men at risk for prostate cancer. Other chemoprevention trials, such as the Carotenoid and Retinoid Efficacy Trial [CARET] and the Alpha-Tocopherol, Beta-Carotene [ATBC] lung cancer prevention study using these agents to prevent lung cancer are also underway.

In fiscal year 1994, the Smoking Prevention and Cessation Program increased by \$5 million. The dominant portion of this increase was provided for the ASSIST program which is a collaborative effort between the NCI, the American Cancer Society [ACS], and 17 state and local health departments to develop and implement the best available strategies to prevent and control tobacco use. The objective is to significantly accelerate the current downward trend in smoking and tobacco use.

A \$12 million increase in fiscal year 1994 was directed to the Chemoprevention Program to include additional preclinical, Phase I, toxicology studies for new chemopreventive agents and Phase II studies for chemopreventive agents. Phase I studies test the toxicities of new compounds, whereas Phase II studies measure the effectiveness of the compounds.

The Diet and Nutrition program expanded by \$2.5 million in fiscal year 1994. Among the program expansions were the NCI's Five-A-Day program which promotes the inclusion of five servings of fruits and vegetables daily into one's diet as a preventive measure. Also, preclinical nutrition research studies were expanded.

The Early Detection Program which includes the Prostate, Lung, Colon and Ovarian study [PLCO] was augmented by approximately \$4 million. This prospective screening trial focuses on the early detection and screening for prostate, lung, colon, and ovarian cancers and is examining the utility of early detection for these cancers.

Other efforts which focus on surveillance activities and special population studies in which targeted cancer prevention strategies are applied were augmented by approximately \$8 million in fiscal year 1994. Cancer surveillance influences the full range of NCI's programs, providing the key evaluative links, and identifying areas of problems and progress. The Surveillance, Epidemiology and End Results [SEER]

Program monitors the cancer burden of the United States by measuring cancer incidence, mortality and survival and assessing the direct and indirect impact of individual and societal factors on such measurements. Surveillance, therefore, provides opportunities for research across the NCI spectrum, from basic research to epidemiology to treatment, to prevention and control.

NATIONAL CANCER INSTITUTE—CANCER PREVENTION AND CONTROL

[In thousands of dollars]

Program	Fiscal year—		
	1992 actual	1993 actual	1994 estimate
Community Clinical Oncology Program [CCOP]	31,450	30,884	39,900
Smoking Prevention and Cessation Program	16,015	22,984	28,000
Chemoprevention activities	19,696	14,497	26,800
Diet and nutrition	13,205	12,020	14,600
Early detection activities	7,406	8,715	12,600
Surveillance program	3,269	3,217	6,100
Biomarkers and prevention research	9,252	5,676	6,500
Special populations studies	2,151	1,946	3,300
Other	5,125	5,154	7,959
Total, cancer prevention and control	107,569	105,293	145,759

CANCER PREVENTION AND CONTROL—1995 INCREASE

Question. Under the President's budget request, fiscal year 1995 funding for NCI would be \$2.19 billion. The 9 percent setaside required by law amounts to approximately \$197 million. Please provide the Committee with detailed spending plans for these funds.

Answer. In fiscal year 1995, the NCI's Cancer Prevention and Control Program will include an increase of \$51,379,000 over fiscal year 1994.

The ability to prevent cancer is, in essence, the primary goal of all of NCI's basic and clinical investigation. To this end, the development of pharmacologic, nutritional, and endocrinologic interventions to inhibit or delay the process of carcinogenesis and the development of effective interventions to modify behavior is of the highest priority. In concert with the expansion of sophisticated biotechnologies, prevention research is increasingly being rooted in a molecular understanding of cancer etiology and the growing body of knowledge about cancer biology.

The identification, development, evaluation, and large-scale testing of interventions directed to prevent, retard or reverse the development of cancer, or to detect the cancer at its earliest and most treatable stages is a primary focus. Intervention strategies may include the use of natural or synthetic substances or behavioral regimens to accomplish biological objectives. They encompass the full spectrum of cancer research, from basic molecular and biochemical investigation to clinical trials, bionutrition studies, and large-scale population-based studies.

Prevention and control also includes research to assure full, effective utilization of research results. To be effective, new knowledge must be put into practice. Consensus on the usefulness of new prevention, detection and treatment regimens does not guarantee their widespread adoption and implementation. Cancer control research addresses this challenge by examining the requirements for full translation of research results into routine practice and by developing the most effective methods to reduce or eliminate barriers to their acceptance. This can incorporate basic social and behavioral science research on individual and organizational factors that affect the application of findings from laboratory and clinical research.

NCI's cancer control research includes a special focus on population groups who bear excessive risks for cancer or who lack access to state-of-the-art cancer prevention and treatment services. The research emphasizes cancer control efforts for these populations directed through government, civic, and private sector health service organizations and professionals who can be mobilized to help them.

Below is a table which details the use of the additional funds proposed for fiscal year 1995. Major areas for emphasis will include:

A \$10 million collaborative effort with the Centers for Disease Control and Prevention will be initiated to further activities associated with breast cancer. Among the efforts to be supported are outreach, training and counseling for at risk populations; genetics and epidemiology studies of breast cancer and the impact of environmental issues on breast cancer.

NCI's Chemoprevention program is sponsoring trials to assess a highly diverse group of biological and chemical agents that have demonstrated anticarcinogenic activity. A fiscal year 1995 expansion of approximately \$7 million is planned and will include a variety of activities involving information processing, data analysis, and developing drug discovery groups to evaluate agents and combinations in preclinical and clinical testing.

The Diet and Nutrition effort will be amplified by over \$8 million in fiscal year 1995 to further investigate diet and nutritional interventions with chemoprevention and epidemiological research to test the role of diet in cancer prevention. The relationship of dietary factors and major cancers, with particular attention to dietary fat and breast cancer, is also under investigation in a large-scale prospective study. Among the major program initiatives is the National 5-A-Day Program, designed to encourage Americans to eat five or more servings of fruits and vegetables every day.

The Smoking Prevention and Cessation program which includes the American Stop Smoking Intervention Study [ASSIST] is slated for a \$3 million expansion in fiscal year 1995. ASSIST is a collaborative effort between the NCI and the American Cancer Society, State and local health departments, and other voluntary organizations to develop comprehensive tobacco control programs in 17 states. Its purpose is to demonstrate that wide-spread, coordinated application of strategies to prevent and control tobacco use will accelerate the current downward trend in tobacco use. Smoking control strategies adapted from science-based models will be implemented as well as cessation support will be delivered to target groups.

The Community Clinical Oncology Program [CCOP] is a network of cancer specialists, primary care physicians, and other health professionals who conduct both clinical treatment research and cancer prevention and control research studies. In fiscal year 1995, this activity will be increased by nearly \$9 million. Primary objectives are the development of clinical trials to affectively implement cancer prevention and control research in multi-institutional settings for early detection and screening, chemoprevention, smoking, patient management, and rehabilitation. Development of cancer prevention and control research in the CCOP network has been increasing, steadily since 1987, with approximately 4,000 patients enrolled annually in these studies. Several large-scale chemoprevention trials are being implemented through this network including the Minority-Based Community Clinical Oncology Program [MBCCOP], initiated to provide minority cancer patients with access to state-of-the-art cancer treatment and control technology.

Within the Early Detection Program, the Prostate, Lung, Colorectal, and Ovarian Cancers [PLCO] intervention trial will be expanded by approximately \$3 million. The PLCO is a 16-year randomized trial in which 37,000 men will be screened for prostate, lung, and colorectal cancers and 37,000 women will be screened for lung, colorectal, and ovarian cancers. Patient accrual began in 1993, with equal numbers of men and women being followed with routine medical care as controls. There will be a 10-year follow-up of participants to determine the effects of screening on disease specific mortality. Diagnostic biopsy specimens will be examined to characterize any genetic alterations. The trial may allow the identification of biomarkers that will pinpoint cancers in their earliest stages. Other Cancer Prevention and Control Early Detection initiatives including additional breast cancer analysis and cervical cancer screening studies will increase by nearly \$4 million.

NCI's Surveillance Program monitors the U.S. cancer burden by measuring cancer incidence, mortality, and survival and assessing individual, societal, and health service factors that mediate these cancer measures. The major component is the Surveillance, Epidemiology, and End Results [SEER] Program, which consists of 11 population-based cancer registries covering 14 percent of the nation's population. This activity is scheduled to increase by over \$1 million in fiscal year 1995.

NCI is committed to addressing the differences among special population groups including minority populations, the underserved, Native Americans, Native Hawaiians, and Native Samoans. Many special projects have been initiated in this regard across the full spectrum of prevention and control initiatives and in fiscal year 1995 an expanded effort will be addressed. For example, a Native American Women's Cancer Initiative was developed in response to the emerging cancer needs and issues of this population. Research goals emphasize the identification of barriers to culturally appropriate cancer control services such as screening, follow-up, diagnostic, treatment and rehabilitation programs for cancers common in or disproportionately elevated among Native American women. Developmental research in Native Pacific populations is being undertaken to assess their cancer prevention, early detection and treatment needs. NCI is supporting outreach activities in the State of Hawaii to reach Native women with information about mammography and cancer early detection to enhance understanding of the unique personal and cultural characteristics of Native Hawaiians that affect their use of cancer early detection tech-

niques, and improve available materials and message appeals to reach and influence this population. Steps have been taken to encourage participation by Native Hawaiians and other underserved populations in clinical trials to ensure that the best possible health care is made available to them.

NATIONAL CANCER INSTITUTE—CANCER PREVENTION AND CONTROL

[In thousands of dollars]

Program	Fiscal year—		
	1994 estimate	1994–94 change	1995 estimate
Community Clinical Oncology Program [CCOP]	39,900	8,788	48,688
Smoking Prevention and Cessation Program ..	28,000	3,205	31,205
Chemoprevention activities	26,800	7,153	33,953
Diet and nutrition	14,600	8,368	22,968
Early detection activities	12,600	6,846	19,446
Surveillance program	6,100	1,087	7,187
Biomarkers and prevention research	6,500	1,052	7,552
Special populations studies	3,300	395	3,695
Other	7,959	4,485	12,444
NCI/CDCC collaborative projects		10,000	10,000
Total, cancer prevention and control	145,759	51,379	197,138

ATAXIA TELANGIECTASIA

Question. Ataxia-Telangiectasia is an inherited multisystem disorder which results from heightened sensitivity to DNA damage from things such as radiation. Children with AT are at great risk for the development of childhood cancers, neurological and immunosuppressive disorders, and frequently die before reaching adulthood.

What is being done in your research program to address the problem of AT? Are you doing cooperative work on this disease with Dr. Francis Collins and the National Center for Human Genome Research?

Answer. Ataxia-Telangiectasia [AT] is an autosomal recessive disorder affecting from 1 in 100,000 to as many as 1 in 20,000 live births. Research into the isolation and characterization of the AT gene is the focus of several teams of scientists here and abroad who are supported by the NCI, the National Institute of Neurologic Diseases and Stroke [NINDS], and the National Center for Human Genome Research [NCHGR]. NCI and NCHGR are also in close collaboration in many areas, including a multi-Institute effort to establish a Diagnostic Genetics Laboratory in which NCHGR is being joined by the National Institute of Diabetes, and Digestive and Kidney Diseases [NIDDK] and the National Institute of Child Health and Human Development [NICHD] as well as NCI.

One of the key abnormalities in AT is a defect in the recombinase enzymes which permit the gene rearrangement and recombination that normally occur in memory cells, namely lymphocytes and neurons. Thus, it is not surprising that the clinical picture of AT involves both clinical immunological and neurological defects.

AT is typified by striking chromosomal fragility of genes involved in the differentiation and function of B and T lymphocytes. Indeed, lymphocytes from individuals with AT, when cultured with an immunostimulant, have breaks in TCR genes in 1 of 8 lymphocytes, while lymphocytes from normal individuals show breaks in only 1 of 1,000 to 1 of 10,000. This fragility is linked to the tragic statistic that more than one-third of patients with AT will develop cancer, particularly lymphoid malignancies. In addition, AT is one of several diseases associated with DNA fragility—Fanconi's anemia, Bloom's syndrome and Xeroderma Pigmentosum, for example—that share net DNA repair deficiency and hypersensitivity to various DNA damaging agents.

This unique chromosomal instability is magnified by defects in repair of DNA strand breaks, a process that depends on the expression of the well-known tumor suppressor p53. Elegant studies by NCI-supported scientists have linked the mechanism of action of the AT gene product to the increase in pg53 gene expression that follows radiation-induced DNA damage. The p53 protein, in turn, induces the expression of certain genes involved in the repair of damaged DNA (so-called GADD genes). It is through the product of the GADD gene that p53 slows the cell cycle and, in effect, permits the cell to repair the DNA damage before it begins to replicate.

In this regard, AT research involves many critical areas of molecular physiology and cellular development that have far-reaching implications for cancers and AIDS: DNA repair; the mechanism of action of p53 (the AT-p53-GADD pathway, described above); radiation sensitivity; recombination and genomic instability (notably lymphoproliferative disorders); and both genetic and acquired immunodeficiencies, including AIDS.

There is a provocative link between women who are heterozygous (carry one copy of the gene) for AT gene abnormalities and breast cancer. AT heterozygosity may occur in up to 2.8 percent of white women in the U.S., and these women appear to have a 5-fold increased risk of developing breast cancer, especially for women under 60 years of age. In sum, AT heterozygosity may account for 8-9 percent of all breast cancer. To further elucidate this potential relationship, NCI is conducting a population-based study in Denmark, where all women are being screened for AT heterozygosity and sensitivity to radiation-induced DNA damage. AT may have another link to breast cancer, this time through pesticides. Indeed, pesticide workers may have AT-like cytogenetic abnormalities in peripheral blood cells. Thus, the study of AT has ramifications regarding the pathogenesis of breast cancer.

NCI, in concert with our sister Institutes, will continue to pursue joint efforts to explore the many facets of AT research. It is anticipated that the results from these basic studies will have broad application to aspects of cancer research as well.

BREAST CANCER

Question. Yesterday there were three separate articles in the New York Times about breast cancer with some disturbing revelations about major NIH sponsored research. The first dealt with possible inaccuracies in the major study which demonstrated that lumpectomies with follow up chemotherapy provided a less destructive effective alternative to radical mastectomies in treating breast cancer. I understand that you have 3 independent investigators looking into the questions raised about the study's accuracy. When should their work be completed?

Answer. There were actually three important trials conducted by the National Surgical Adjuvant Breast and Bowel Project [NSABP] that have been influential in guiding the choices of women with breast cancer and their physicians. The first of these trials, referred to as NSABP B-06, compared lumpectomy, simple (not radical) mastectomy, and lumpectomy plus local radiation. (A very early NSABP trial had found that simple mastectomy afforded the same survival as the long-held standard radical mastectomy.) The key point is that women can select breast-sparing procedures for breast cancer. This was not always the case.

The second trial (B-13) compared the effect of chemotherapy adjuvant vs. no chemotherapy following initial surgery in node-negative women (i.e., no cancer found in axillary lymph nodes following axillary lymph node dissection). The third trial (B-14) compared the effect of tamoxifen vs. placebo as adjuvant therapy following initial surgery in node-negative women. These trials concluded that (1) lumpectomy is an effective alternative to simple mastectomy; (2) chemotherapy decreases relapse rate and improves survival; and (3) tamoxifen decreases relapse rate and modestly improves survival.

The conclusions of each of these trials have been corroborated by independent clinical trials. An additional five independent randomized clinical trials conducted in the United States and in Europe comparing lumpectomy with mastectomy have concluded that survival is similar following lumpectomy or mastectomy. A "meta-analysis" of all the world's randomized clinical trials of adjuvant chemotherapy and tamoxifen confirm that either chemotherapy or tamoxifen improves survival in both node-negative and node-positive women.

Dr. Poisson of St. Lucs Hospital Montreal contributed substantial numbers of patients to each of these trials, including 16 percent of the entered patients on the B-06 trial. When the falsification of data by Dr. Poisson was first discovered in 1990 and verified after further investigation in 1991, the NSABP performed a reanalysis of the data from each of the three trials after removing all patient data contributed from St. Lucs Hospital. The conclusions for each trial remained the same and in fact, were numerically almost identical. This reanalysis has been submitted by the NSABP for publication to the New England Journal of Medicine. When the documents constituting the reanalysis were transmitted to the NCI in February 1994, Dr. Richard Simon, Chief of the Biometric Research Branch of NCI's Clinical Therapy Evaluation Program [CTEP] reviewed the report in conjunction with some of the original publications; he agreed that the analysis was supportive of the original conclusions, but asked for clarification and extension of certain aspects of the analysis. In addition, NCI has sent the summary reanalysis to three outside statisticians (Richard Gelber of the Harvard School of Public Health, Joseph Pater of the Na-

tional Cancer Institute of Canada, and David Harrington of the Dana-Farber Cancer Institute). So far, responses from Dr. Gelber and Dr. Harrington have been received, and they support the conclusions of the reanalysis.

As an additional confirmatory step, the computer data files for certain key NSABP studies have been analyzed by statisticians under contract to NCI. They have obtained the same results for B-06 as were found by NSABP in their reanalysis (i.e., lumpectomy, lumpectomy plus radiation, and mastectomy all yield comparable survivals). A copy of this report has been provided to the Subcommittee. The reanalysis of B-13 and B-14 are underway, and will be provided to the Subcommittee within the next several weeks. A primary audit of the files against the original research record is underway. NCI has initiated on-site audits of the primary patient eligibility data for the B-06 trial (breast sparing surgery) to further assure that the conclusions are valid. If discrepancies are found in these primary data and related data files, we will make our findings known immediately and widely. Fraud is a terrible thing. It is very sad that a surgeon in Canada chose to do things that have significantly affected what we do. We are working to devise better audit procedures to expose fraud early. We would be happy to brief the Committee on what steps we are taking.

BREAST CANCER

Question. I am even more concerned about new information that raises questions about the advisability of giving healthy women tamoxifen as a preventive measure. These studies have found that more harm than good might come to healthy women because of increased risk of fatal uterine cancer as a side effect of taking tamoxifen. We're funding a massive clinical trial in this area. What are you doing to assure that it is appropriate to continue these studies? Also, the New York Times article raised a very good point—that NCI tends to trumpet positive developments, like the press conferences kicking off the tamoxifen trials, but may play down equally important negative findings like these new studies raising questions about tamoxifen. How do you respond to that?

Answer. We know from treatment trials that tamoxifen can prevent new breast cancer. In the Breast Cancer Prevention Trial [BCPT], we are focusing on the net balance between potential benefits and risks from tamoxifen in women who are at increased risk for breast cancer.

I must underscore that the BCPT, if successful, will offer women a choice for preventing breast cancer. Today, a woman at high risk (for example, a woman with lobular carcinoma in situ has 13 times the risk of a woman without any risk factors—a 50 percent probability of developing breast cancer over the next 20 years) has only two choices: prophylactic mastectomy or watchful waiting. The fact that tamoxifen has been very effective in reducing the incidence of new cancers in women with breast cancer is the major impetus for the BCPT. Tamoxifen also appears to reduce the incidence of cardiovascular disease and osteoporosis, while increasing the risk of endometrial cancer.

We believe the important question for women at high risk of breast cancer is whether the increased risk of endometrial cancer (which is about the same level of increased risk as experienced by a woman taking hormone replacement therapy for menopausal symptoms) is outweighed by reduction in breast cancer as well as the reduction in cardiovascular risk and osteoporosis.

We continue to review the worldwide literature on tamoxifen, and as new information becomes available about additional benefits or risks, we calculate new estimates for risks and benefits. These estimates are placed before the BCPT advisory committees and the NCI leadership, as well as the public and of course, the women participating in the trial, all as part of the ongoing safety monitoring program. In late February of this year, the BCPT End Result Safety Monitoring and Advisory Committee [ERSMAC] and the BCPT Steering Committee reviewed the new information on endometrial cancer. Both concluded that the benefits of tamoxifen continued to outweigh the risks and that the BCPT should continue as planned.

Regarding publications of risk-benefit analyses, we have reviewed these analyses and found that when corrections are made for various factors, the expected benefit of tamoxifen outweighs the risks. We believe, therefore, that the BCPT trial should continue, because it is only through this trial that we can address these uncertainties. Nevertheless, we will be discussing these issues with NCI's Division of Cancer Prevention and Control's Board of Scientific Counselors at a special session of their main meeting that will be held in May. The Board will review estimates of risks and benefits based on the literature, review recent clinical studies, and provide guidance to the Institute on the future direction of the trial. In particular, the Board will consider whether a change in eligibility criteria is appropriate. To date, women

entering the trial are at considerably higher risk than anticipated. While reflecting a decision by the public, striking an appropriate balance between particular individuals at high risk of breast cancer and the potential benefits and risk of a tamoxifen preventive regimen.

Please note that the risk of uterine cancer has been recognized from the beginning of BCPT planning and implementation. Women have always been informed of this increased risk prior to their enrollment in the study. The new information about endometrial cancer occurrence in the NSABP B-14 trial is consistent with the risk information presented to potential participants in the original informed consent documents: approximately a two-to-three-fold risk of endometrial cancer associated with tamoxifen use. The informed consent has now been changed to express this risk as a rate (about two cases per 1,000 women per year), and to add that endometrial cancer is potentially lethal, although most cases associated with tamoxifen has been diagnosed at an early stage and have had effective therapy. Nevertheless, all would agree that tamoxifen must be used with respect.

Also, from the onset of the trial, a normal gynecologic examination has been required prior to study entry. In addition, to assure that any endometrial abnormalities occurring among participants are detected early in their course, participants are queried about gynecologic symptoms at each follow-up and annual gynecologic examination. Endometrial biopsies are encouraged but are not required for all participants. In addition to routine monitoring of all BCPT participants, a detailed study of endometrial effects of tamoxifen will be conducted among a subgroup of BCPT participants.

It is NCI policy to report negative as well as positive findings from research studies and to also provide as complete information about ongoing trials as possible. For example, at the initial press conference for the BCPT, the increased risk of endometrial cancer was stated in a public forum. The media were present to hear the discussion of the risks and benefits, including endometrial cancer. The press package of Questions and Answers included a clear statement of the increased risk. In addition, the theoretical risk of liver cancer was stated in the press package, despite the fact that there has never been a clear association between tamoxifen use and liver cancer. Certainly, as any new data became available, they were incorporated into the informed consent documents for the BCPT. Likewise, the publication of the paper describing increased risk of endometrial cancer and of deaths from endometrial cancer in the B-14 trial was expedited in order to make it available to the public as quickly as possible.

In regard to our public announcements, NCI tries to provide information about both benefits and risk, good news and bad. We are very sorry if NCI has caused the impression of focusing only on good news, and we will accept the constructive criticism as we map our course for the future. It has been NCI's policy to provide an annual review of cancer statistics emphasizing mortality increases as well as mortality decreases. At a recent meeting of the President's Cancer Panel reviewing progress against cancer, an NCI official presented a paper reviewing nearly 20 years of statistics on cancer, emphasizing that overall cancer incidence continues to climb, and along with it, cancer mortality, albeit at a slower rate of increase. These statistics highlighting areas of problems and progress are discussed extensively with the press.

As another example, as soon as the NCI became aware that the Canadian National Breast Screening Study was nearing publication, we began planning the International Breast Cancer Screening Workshop, despite the fact that the results were not in concert with our prior very public recommendations in favor of mammography screening for young women. The Workshop was held in full public view, with people from the media present to hear the discussion of all breast screening studies, including their weaknesses. When it was clear that the state of knowledge regarding screening was no longer in agreement with our guideline, we made this knowledge public, we subsequently held open meetings twice as part of the National Cancer Advisory Board and once with the Division of Cancer Prevention and Control's Board of Scientific Counselors. Again, the media were invited and fully covered the hearing.

One final word about tamoxifen: we do not ever intend to recommend the use of tamoxifen on a broad basis to prevent breast cancer. We do, however, hope to find out if certain women who face what they properly feel is an unacceptable risk of breast cancer can have additional options other than just letting fate take its course. That is why we want to have the results of a randomized clinical trial to help us.

Science can only progress if both positive and negative results of research are presented. NCI understands its obligation to keep the public as fully informed of all aspects of cancer research as possible. We appreciate the Senate's support.

QUESTIONS SUBMITTED BY SENATOR MACK

EARMARKS FOR BIOMEDICAL RESEARCH

Question. The President's proposal emphasizes funding for breast cancer research. I'm very sensitive to this, as my wife and mother are both breast cancer survivors. Yet, if one looks at incidence, mortality and funding levels of breast cancer versus prostate cancer, or other forms of cancer which are prevalent in women, the numbers appear skewed. This is due, in large part, to Congressionally-mandated earmarks resulting from pressure from outside groups and organizations. While there were no earmarks in last year's NIH appropriation's bill, the President's budget once again attempts to start Congress down the path of earmarking biomedical research.

How do you view the issue of earmarking of biomedical research funding? What difference did it make last year that there were no earmarks? Shouldn't these decisions be left to the research community?

Answer. NCI believes that we should be responsive to the priorities as articulated by the Congress in that they represent the wishes of the American people. As a public service organization and one that is funded through the taxpayers' dollars, we recognize and fully accept the need to take these wishes into account as we develop research priorities for the Institute.

However, it is also true that it is important to maintain maximum flexibility in setting research goals. Basic, untargeted research has always provided the scientific underpinning which makes the targeted research advances possible. In addition, because scientific advances and research breakthroughs may be unpredictable, maximum flexibility allows the Institute to quickly pursue promising research leads. This is prudent scientific management in that we can better achieve our goals when we are able to make the changes necessary to capitalize on recent advances that have an overarching application to other areas of scientific research.

In fiscal year 1994, there was no earmarking for NCI-supported areas of research. However, we trust that, at this time when we give an accounting of our stewardship, that you are pleased with the priorities that we have set and our achievements to date. We appreciate your confidence and support and we will continue to work in joint partnership with the Congress and the overall scientific community so that together we can achieve our mutual goals.

PROGRAM COORDINATION

Question. Being a staunch supporter of both prevention and research activities, specifically cancer-related, I worked with this subcommittee to include language within the fiscal year 1994 Senate Report to urge coordination between the Centers for Disease Control, NIH and other PHS agencies to develop a program of coordination to insure the best utilization of Federal resources for cancer control and research activities. Has this coordination been implemented and if so, how? If not, why?

Answer. The NCI actively collaborates and coordinates research with the Centers for Disease Control and Prevention [CDCP] in many areas. Significant interactions occur with CDCP subordinate agencies, i.e., the National Institute for Occupational Safety and Health [NIOSH], and the National Center for Health Statistics [NCHS]), other NIH sister institutes, e.g., the National Institute of Environmental Health Sciences, other PHS agencies as well as the Food and Drug Administration. There has been a long-standing research collaboration with NIOSH to investigate occupational causes of cancer, and we continue to work with NCHS in developing and utilizing its files for a large variety of cancer-related activities. NCI has ongoing initiatives and continues to collaborate with the Indian Health Service in cancer etiology studies of American Indians and Alaskan Natives.

Intra-PHS collaborations are particularly prominent in the portfolio of the Healthy People 2000 initiatives. The strong NCI program directed toward the needs of Special Populations involves both CDCP and the Office of Minority Health. A project in the District of Columbia on the primary and secondary prevention of oral cancer is indicative of this close cooperation. As another example, the collaboration of NCI with CDCP along with the American Cancer Society on the American Stop Smoking Intervention Study [ASSIST] is central to NCI's strategy to achieve major reductions in smoking prevalence.

NCI has an interagency agreement for a Collaborative Program on Environmental Cancer with the Environmental Protection Agency [EPA].

NCI holds regular meetings with CDCP's Office on Smoking and Health for the purpose of coordinating tobacco initiatives. An example of NCI/CDCP collaboration

includes the development and dissemination of a smokeless tobacco videotape directed at adolescents.

The NCI in collaboration with the CDCP and the FDA, have developed a Strategic Plan for the Early Detection of Breast and Cervical Cancers. The plan was developed with the help of over 100 organizations and through two national meetings. We expect the Plan to serve as a stimulus and template for local activities, as well as a guide for Federal activity. The three agencies have committed staff to implementing the Plan and are scheduling a meeting of a national steering committee for September and regional meetings during fiscal year 1994. NCI's Surveillance Program staff are active participants on inter-agency task forces developing surveillance plans for screening of cervical and breast cancer. Membership is drawn from numerous public health service agencies, such as CDCP and the FDA. Surveillance Program staff participate in interagency efforts to develop plans for implementing the recently passed Mammography Quality Standards Act. An NCI senior staff member is the Institute's representative for the Interagency Forum on Aging-Related Statistics.

Surveillance activities are discussed frequently between NCI through its Surveillance, Epidemiology and End Results Program and the CDCP. Members of NCI's Surveillance Program met with the CDCP to assist them in its plans to implement the Cancer Registry Bill.

NCI has worked with the CDCP on its National Health Interview Survey, sponsoring a cancer control component. The 1987 Survey was extremely successful and serves to define the baseline for much of our cancer prevention and control effort.

There is frequent contact with CDCP to interface and coordinate public information materials and strategies regarding issues of concern including breast and cervical cancer screening.

NCI is conducting with CDCP and other PHS agencies a study of human health consequences of polybrominated biphenyls (PBB) contamination of farms in Michigan to provide long-term health follow-up of persons highly exposed to PBB through contamination of animal feed. NCI also utilizes the laboratory expertise available at CDCP for the analysis of environmental contaminants (e.g., pesticides and PBB's) and micronutrients (e.g., vitamins A, E and C) in biological specimens collected in cancer epidemiology studies.

Below are identified a listing of interactions among the NCI and various other components of the government in areas of mutual and complementary interest and responsibility:

Interagency Collaborative Group on Environmental Carcinogenesis

This group was organized by the National Cancer Institute over 17 years ago and serves as a vehicle for information exchange in the area of environmental cancer. Member agencies are as follows: Armed Forces Institute of Pathology; Centers for Disease Control and Prevention; Consumer Product Safety Commission; Department of Energy; Department of Labor/Occupational Safety and Health Administration; Department of Transportation; Environmental Protection Agency; Food and Drug Administration; National Institute of Standards and Technology; National Center for Health Statistics; National Institute of Environmental Health Sciences; National Library of Medicine; National Toxicology Program; Smithsonian Institution; U.S. Army Biomedical Research and Development Laboratory; U.S. Department of Agriculture; and U.S. Department of Commerce.

Chemical Selection Working Group

This group, sponsored by NCI, evaluates chemicals to ascertain whether or not they have a potential of inducing cancer in an exposed population. After evaluation, candidate chemicals are nominated to the National Toxicology Program (NTP) for further testing. Member agencies are as follows: Centers for Disease Control and Prevention; Consumer Product Safety Commission; Department of Commerce; Department of Labor/Occupational Safety and Health Administration; Environmental Protection Agency; Food and Drug Administration; Interagency Testing Committee; National Institute for Child Health and Human Development; National Institute of Environmental Health Sciences; National Institute for Occupational Safety and Health; National Library of Medicine; National Toxicology Program; Oak Ridge National Laboratory; U.S. Army—Aberdeen Proving Grounds; U.S. Army Biomedical Research and Development Laboratory; and U.S. Department of Agriculture.

Task Force on Cancer, Heart and Lung Disease

Section 402 of Public Law 95-95, Clean Air Act Amendments of 1977, established this task force to provide "Interagency Cooperation of Prevention of Environmental Cancer and Heart and Lung Disease." It is chaired by the Environmental Protection Agency with NCI being a member agency of this group. Other agencies represented

are as follows: Agency for Toxic Substances and Disease Registry; Centers for Disease Control; Consumer Product Safety Commission; Department of Defense; Department of Energy; Department of Labor/Occupational Safety and Health Administration; Environmental Protection Agency; Food and Drug Administration; National Center for Health Statistics; National Heart, Lung, and Blood Institute; National Institute of Environmental Health Sciences; National Institute for Occupational Safety and Health; National Library of Medicine; U.S. Department of Agriculture; and Department of Veterans Affairs.

Interagency Testing Committee

The U.S. Congress created the Interagency Testing Committee [ITC] under the Toxic Substances Control Act [TSCA] to recommend TSCA regulable chemicals and chemical groups to the Administrator of the U.S. Environmental Protection Agency [EPA] for Priority Testing consideration. NCI is a member agency. Other agencies are: Agency for Toxic Substances and Disease Registry; Consumer Product Safety Commission; Council on Environmental Quality of Agriculture; Department of Commerce; Department of Defense; Department of the Interior; Department of Labor/Occupational Safety and Health Administration; Department of Transportation; Environmental Protection Agency; Food and Drug Administration; National Cancer Institute; National Institute for Environmental Health Sciences; National Institute for Occupational Safety and Health; National Library of Medicine; National Science Foundation; National Toxicology Program; and U.S. International Trade Commission.

Committee to Coordinate Environmental Health and Related Programs [CCEHRP]

Subcommittee on Information Coordination.—Facilitates the coordination and exchange of information in technology, environmental health and related areas among CCEHRP member agencies and, where appropriate, other agencies of the government. NCI is a member agency. Other agencies are: Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Department of the Army; Department of Labor/Occupational Safety and Health Administration; Food and Drug Administration; National Center for Health Statistics; National Cancer for Toxicological Research; National Institute of Environmental Health Sciences; National Institute of Mental Health; National Institute for Occupational Safety and Health; National Library of Medicine; National Technical Information Service; Oak Ridge National Laboratory; U.S. Consumer Product Safety Commission; U.S. Department of Agriculture; and U.S. Fish and Wildlife Service.

Subcommittee on Environmental Risk Communication and Education.—Coordinates information dissemination for, and provide reviews of communications and education efforts relevant to identified environmental hazards. NCI is a member agency. Other agencies are: Agency for Toxic Substances and Disease Registry; National Institute on Alcohol Abuse and Alcoholism; Centers for Disease Control and Prevention; Environmental Protection Agency; Food and Drug Administration; Health Resources and Services Administration; National Center for Health Statistics; National Institute of Environmental Health Sciences; and National Institute for Occupational Safety and Health.

Interagency Taskforce on Human Exposure Assessment.—Cooperate and coordinate on important issues associated with human exposure assessment. NCI is a member agency. Other agencies are: Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Department of Energy; Environmental Protection Agency; Food and Drug Administration; National Center for Health Statistics; National Institute of Environmental Health Sciences; and National Institute for Occupational Safety and Health.

Working Group for the Annual Report on Carcinogens.—Evaluates the list of candidate substances and accompanying data considered for inclusion in this report. NCI is a member agency. Other agencies are: Centers for Disease Control and Prevention; Consumer Product Safety Commission; Department of Labor/Occupational Safety and Health Administration; Environmental Protection Agency; Food and Drug Administration; National Institute of Environmental Health Sciences; National Institute for Occupational Safety and Health; and National Library of Medicine.

CLINICAL CENTER STUDY SECTION

Question. Dr. Broder, would you like to respond to the questions I asked Dr. Varmus regarding the need for a separate Clinical Cancer Study Section?

Answer. An important criterion of non-prejudicial peer review is the provision of a broad base of scientific expertise and perspectives that are designed to achieve a balanced assessment of the proposed research. Such a mixture of general and fo-

cused scientific acumens will serve to overcome unconscious personal biases, either positive or negative. In this regard, the principles of peer review for clinical cancer investigation are the same as basic science with the aim of providing fair competition for funding based on knowledge of the needs and factors surrounding research in general.

My feeling is that we must be poised to apply the best clinical research that seeks to extend new findings in basic science to the bedside and that recognizes clinical anomalies which may give new insight into basic processes. Reviewers thus always need to be aware of all parts of the continuum between basic and clinical science. Nevertheless, the variability introduced by working with human research subjects is sufficiently different from the more controllable aspects of basic research to warrant a peer group experienced in clinical investigations, and I would encourage the Division of Research Grants to continue its exploration of ways to group the review of such applications.

Some of the issues in working with cancer patients are unusual enough, if not unique, to warrant use of reviewers with direct knowledge of these distinctions. Absence of such expertise in sufficient strength could cause questions relevant to ratings. Interestingly, when the NCI holds special competitions for research on a single clinical topic and seeks reviewers who are all expert in clinical research, often the review results show that many applications do not score particularly well on an absolute scale.

ENVIRONMENTAL RESEARCH

Question. The NCI has undertaken extensive research into possible environmental causes of cancer. Specifically, NCI is investigating areas such as pesticides and other toxic chemicals, air pollution, hazardous waste, electromagnetic fields and other environmental hazards. Are we doing enough research in this area? What are the long-range research initiatives planned by NCI in this area?

Answer. NCI considers environmental carcinogenesis to be a research area of high priority and actively supports intramural and extramural research programs to identify and evaluate the environmental causes of cancer. In fiscal year 1993, NCI devoted \$309 million to research in this area, and projects to spend \$333.6 million in fiscal year 1994. Research on possible environmental causes of cancer involves chemical and physical carcinogenesis, biological carcinogenesis, and epidemiology research focused on etiologic risk factors.

Although NCI pioneered efforts in the field of toxicology testing early in the 1970's, NCI does not now do routine carcinogenicity testing of chemicals in mice and rats. In 1981, the responsibility for managing the Carcinogenesis Bioassay Program and the necessary resources (including \$44 million and 95 positions) were transferred from NCI to the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences (NIEHS). This transfer provided for direct management and allowed NIEHS to look not only at the carcinogenic effects of chemicals, but also to study their effects on the reproductive system, the nervous system, and behavior as well as other effects. Currently, NCI is a member of the NTP Executive Committee and nominates the great majority of chemicals for high priority testing. These nominations are based on environmental exposures, occupational exposures, production data, structural relationships to known carcinogens and in vitro mutagenicity tests. Approximately 60 percent of the compounds tested by NTP are from nominations submitted by NCI. NCI has had and continues to have a good relationship with the NTP and the NIEHS.

In addition, NCI continues to perform carcinogenicity testing in nonrodent species and to perform selective carcinogenicity tests. For example, NCI is carrying out studies in specialized systems such as a chemical carcinogenesis project in macaques evaluating a number of potential environmental carcinogens including heterocyclic amines found in cooked foods, a transplacental carcinogenesis project in patas monkeys, a study on solid state carcinogenesis in rodents to clarify risks associated with breast implants, studies of lung tumor induction by silica and other particulates in rodents, and studies of carcinogenesis in non-mammalian species such as fish and bivalves.

NCI also performs and supports a variety of environmental carcinogenesis studies to learn more about activation of carcinogens, chromosome alterations, mechanisms of epithelial carcinogenesis, and tumor promoters. Other research concentrates on species susceptibility to chemical carcinogens including specific patterns of oncogene activation, characterization of cell culture systems for response to chemical and physical carcinogens, cancer susceptibility in certain families, and epidemiologic studies of environmental determinants of cancer and of selected occupational groups to help identify chemical and physical carcinogens.

Cancer excesses have been identified in certain occupational groups, such as farmers, who have been exposed to pesticides and other potentially harmful compounds. A population-based case control study in Nebraska found that farmers using the phenoxyacetic acid herbicide, 2,4-D, had a higher risk for non-Hodgkin's lymphoma (NHL) and a significant exposure-response trend with frequency of use. The risk of NHL rose with the frequency of use of 2,4-D to over threefold among farmers reporting use for 20 or more days per year. Other occupational studies have linked heavy exposures to asbestos and radon to increased risk of lung cancer. Cigarette smoking also can interact with asbestos and radon to increase the risk of lung and possibly other cancers among exposed persons.

Fumigants, another group of pesticides under suspicion as human carcinogens, are widely used in the grain industry to control damage from insects. A recent study on workers in the grain industry uncovered excess mortality from NHL, leukemia, and pancreatic cancer. Among the fumigants to which the workers may have been exposed are ethylene dichloride, ethylene dibromide, malathion, phostoxin and carbon tetrachloride. Workers employed in flour mills, where use of grain fumigants is heavy, had four times the risk of NHL and twice the risk of leukemia and pancreatic cancer as those employed in other segments of the grain industry.

Scientists at NCI and NIEHS are assessing breast cancer risk on cohorts of women exposed to extremely high levels of polybrominated biphenyls, DDT and hexachlorobenzene (a grain fumigant) to determine whether the levels of organochlorine compounds in tissue of breast cancer cases differ from those in controls. In collaboration with NIEHS and the Environmental Protection Agency, NCI has launched the largest ever epidemiologic study of farmers and their families in the United States. This 10-year prospective study, involving about 100,000 farmers and their family members, will examine both cancer and non-cancer outcomes. A variety of exposures (e.g., agricultural chemicals, solvents and engine exhausts) to which the general public comes into contact will be investigated. Another initiative involves migrant and seasonal farmworkers, who encounter a large variety of toxic agricultural exposures. Because of the nature of this type of farmwork, special methods need to be developed to identify cancer cases among this population and to characterize their exposures.

Another major long-term initiative involves studies on environmental and other causes of breast cancer, particularly in high-rate regions of the country. Toward this end, NCI has launched several interrelated studies of breast cancer in the Northeast and Mid-Atlantic states, with a separate but complementary concentrated effort in Nassau and Suffolk counties on Long Island, New York. Among environmental exposures of interest are pesticides, toxic chemicals, electromagnetic fields, ionizing and ultraviolet radiation, dietary components, water pollution and natural and synthetic estrogens. NCI also plans to continue efforts to evaluate cancer risks associated with general environmental exposures, such as drinking water contaminants (e.g., nitrate, arsenic and chemical byproducts of water chlorination), air pollution (e.g., industrial and automobile emissions) and electromagnetic fields (e.g., power lines and home appliances).

Studies in radiation carcinogenesis investigate the biological effects of low doses of various forms of ionizing and non-ionizing radiation, including low-frequency electromagnetic radiation, ultraviolet irradiation from the sun, radon, and x-rays. The role of exposure to residential and nonresidential electromagnetic radiation from electrical lines in the development of childhood acute lymphoblastic leukemia is an ongoing area of study. The risk of cancer from radon exposure has received considerable attention, and new risk models that accommodate population mobility and occupancy suggest that indoor radon may be less of a public health hazard than was previously estimated using extrapolations from data on uranium miners who received high radon exposure; a long-term study that uses improved dosimetry should provide new insights on levels of risk from residential radon.

Other studies are underway to examine the risk for brain cancer in connection with the non-ionizing electromagnetic radiation released by a number of appliances. Existing databases are being studied for pertinent information, and case-control studies and cohort investigations of exposed populations are anticipated. A major comprehensive case-control study to assess the exposures of adults recently diagnosed with brain cancer began last year. A wide variety of exposures will be evaluated, and the potential risks of cellular phones will be thoroughly assessed.

Through recent investigations in China, NCI scientists are clarifying the role of air pollution in lung cancer risk. In one study in Shenyang, lung cancer risk rose in proportion to exposure to indoor air pollutants from coalburning stoves and other home-heating devices. Outdoor air pollution was also found to be related to lung cancer risk, with an effect of residential exposures to inorganic arsenic suggested by a higher risk among men living within one kilometer of the central stacks of a

large Shenyang copper smelter. This finding is consistent with an earlier NCI study linking lung cancer risks in the U.S. to community as well as to occupational exposure to arsenic air pollution.

Although traditionally considered the sine qua non of biological carcinogenesis, transforming viruses are also environmental carcinogens. There are a number of DNA viruses that are etiologically associated with human cancers, namely human papillomaviruses [HPV], Epstein-Barr virus [EBV] and the hepatitis viruses [HBV and HCV]. These viruses may cause certain cancers directly, as in the cases of EBV and nasopharyngeal carcinomas or so-called endemic (African form) Burkitt's lymphomas. Alternatively, a transforming virus may interact with another environmental factor to yield a striking predisposition to specific malignancies. For instance, in some regions of China and southern Africa, HBV may cooperate with aflatoxin B₁, a carcinogenic fungal byproduct that contaminates some foods, to produce a high incidence of liver cancers. The risk for developing cervical cancer may increase as a result of synergy between a transforming strain of HPV and co-infection by herpes simplex virus [HSV]-2. Cooperation among various non-viral environmental factors and tumor-initiating transforming HPV strains may be of paramount importance to the full-blown development of cervical cancer, e.g., cigarette smoking or dietary micronutrient deficiencies (folate and/or vitamin A derivatives).

In addition, retroviruses (or RNA viruses) also cause certain cancers directly, as in the case of human T lymphotropic viruses [HTLV]-1 and -2, or perhaps indirectly in concert with transforming DNA viruses, as in the case of human immunodeficiency virus [HIV] and certain acquired immunodeficiency syndrome [AIDS]-related malignancies. Examples in this latter group include aggressive EBV-associated lymphoproliferative malignancies and HPV-associated anogenital malignancies in HIV-infected men and women. Animal models of cancers induced by DNA and RNA viruses provide some parallels to the human condition—mouse mammary tumor virus and certain animal retroviruses such as feline leukemia virus, as examples—and thus offer an opportunity to study disease pathogenesis and prospective interventions. These research targets are not included in the fiscal data for environmental carcinogenesis research, but represent an important direction for NCI's intramural and extramural research portfolio, nonetheless.

NCI also is conducting and supporting research on a species of bacteria called *Helicobacter*. One member of this group of bacteria, namely *Helicobacter pylori*, showed a higher level of infection in several studies of gastric cancer patients than in matched control groups and supports the conclusion that there is an association between *H. pylori* infection and gastric cancer. Another new member of this group, called *Helicobacter hepaticus*, has been shown to cause liver cancer in several strains of mice. Therefore, long-term studies are being carried out on this emerging pathogenic species.

NCI will continue to support and fund intramural and extramural research on environmental causes of cancer, utilizing the basic project grant (RO1) and other funding mechanisms. Grantees are pursuing research in all areas of environmental carcinogenesis and epidemiology, including genetic susceptibility factors, to understand the mechanisms by which environmental exposures cause cancer. One recent NCI initiative encourages grant applications to investigate occupational exposures as causes of cancer, with special emphasis on approaches for cancer control in workplace settings, especially among minority populations and women. Finally, an important and growing body of research supported by NCI is seeking ways to prevent or modify the untoward effects produced by toxic environmental chemicals.

ATAXIA TELANGIECTASIA

Question. I recently met with a constituent from Florida, Brad Margus, who has three sons. Two have been diagnosed with AT. He explained that this rare disease affects many body functions and is linked to cancer in children as well as immunological and neurological diseases. I know he's met with Dr. Collins (Genome), he has met with researchers at NCI, and served with Dr. Grady (Neurological Disorders and Stroke) as a panelist on Larry King Live last week. What research opportunities exist in this area and how will the various institutes coordinate their efforts?

Answer. AT research involves many critical areas of molecular physiology and cellular development that have far-reaching implications for cancers and AIDS: DNA repair; the mechanism of action of p53; radiation sensitivity; recombination and genomic instability (notably lymphoproliferative disorders); and both genetic and acquired immunodeficiencies, including AIDS.

Mr. Brad Margus, founder of the AT Children's Project, met with NCI officials in March 1994 to discuss scientific issues and mechanisms to foster AT research. Top-

ics of discussion included: establishment of AT cell lines; creation of an "AT Network" of investigators for call exchange and yearly meetings; a small meeting to bring in new faces and ideas; p53 and cell cycle research; other syndromes involving DNA fragility and defective DNA repair (e.g., Xeroderma Pigmentosum and Bloom's Syndrome); DNA methylation as a modulator of AT gene expression; mediators of neuronal cell death (nitric oxide) vs. survival (bcl-2); and gene therapy techniques (once the gene is found). Mr. Margus was encouraged to consider application to NCI for an R13 (or Conference) grant to help support a multidisciplinary meeting on AT and disorders of DNA repair, perhaps at such time as the gene is definitively identified and cloned.

The AT Children's Project, founded by Mr. Margus in July 1993, currently funds eight grants: six focus on cloning of the AT gene, one focuses on cell cycle control in AT post-irradiation and one focuses on molecular analysis of cellular responses to ionizing radiation in AT. In fact, one of Mr. Margus's grantees from Israel is actively collaborating with an NCHGR investigator in studies to clone the AT gene.

Research into the isolation and characterization of the AT gene is the focus of several teams of scientists here and abroad who are supported by the NCI, the National Institute of Neurologic Diseases and Stroke [NINDS], and the National Center for Human Genome Research [NCHGR]. NCI and NCHGR are also in close collaboration in many areas, including a multi-Institute effort to establish a Diagnostic Genetics Laboratory in which NCHGR is being joined by the National Institute of Diabetes, and Digestive and Kidney Diseases [NIDDK] and the National Institute of Child Health and Human Development [NICHD] as well as NCI.

NCI has a long history of involvement in AT research. In 1972, an NCI scientist along with another NIH scientist (a neurologist at the National Institutes of Health [NIH]) were the first to recognize the multisystem involvement characterizing AT and the ability to use serum alpha-fetoprotein as a marker of disease. In addition, the ongoing studies in molecular genetics on p53 and GADD genes have resulted from collaborations between NCI scientists and investigators at Johns Hopkins.

Research suggests a link between women who are heterozygous (carry one copy of the gene) for AT gene abnormalities and breast cancer. AT heterozygosity may occur in up to 2.8 percent of white women in the U.S., and these women appear to have a 5-fold increased risk of developing breast cancer, especially for women under 60 years of age. In sum, AT heterozygosity may account for 8-9 percent of all breast cancer. To further examine this potential link to breast cancer, NCI is conducting a population-based study in Denmark, where all women are being screened for AT heterozygosity and sensitivity to radiation-induced DNA damage. Other studies have shown that pesticide workers may have AT-like cytogenetic abnormalities in their peripheral blood cells. It is likely that the study of AT will provide new insights into the pathogenesis of breast cancer.

QUESTIONS SUBMITTED BY SENATOR STEVENS

CERVICAL CANCER SCREENING IN ALASKAN NATIVE WOMEN

Question. In preparing for this hearing, and in talking with my Alaskan Native constituents in the last few weeks, I could not help but review the issues of our very high rates of certain forms of cancer among Alaskan Natives: For instance, in Alaskan Native men, our rates continue high in lung, colorectal, and either stomach or colorectal cancer, depending on the year.

For Alaskan Native women, we cannot escape the conclusion that we must do something about their rates of cervical cancer. While they have relatively low rates of breast cancer, about half the rate of all races in the United States, the rate of invasive cervical cancer in Alaskan Native women is two-and-a-half times the rate in the general population. More critically, the death rate is two times that of the general population.

What disturbs me most is that invasive cervical cancer has usually been seen in women in their fifties, and it takes 10 to 12 years for the cancer to progress to that point. In Alaska, invasive cervical cancer is being seen in very young Alaskan Native women.

We believe that these rates of early invasive cervical cancer may be due to strains of the human papilloma virus which occur more frequently in the Alaskan Native population. A great deal of this finding may be due to the abuse that combines alcohol and child sexual abuse, and a great deal to unprotected sex in a population with problems of too early childbearing, and a birth rate of 3 percent, which rivals Mexico and Bangladesh.

As a result of these striking findings, and my understanding that screening is not available in our villages, but only in our hub communities, how can we best encourage Alaskan Native women to be screened for cervical cancer?

Answer. NCI is working to improve Alaskan Native women's knowledge and understanding of the risks of cervical cancer and the process for preventing mortality from this disease. This effort has included the development of cancer education programs that are culturally relevant and the dissemination of the latest materials and research findings to health care providers. Partnerships have been developed with State and local health departments as well as with other federal agencies such as the Centers for Disease Control and Prevention and the Indian Health Service. Some of the ongoing programs that relate to cervical cancer are described below.

NCI is supporting a very important initiative, the Avoidable Mortality from Cancers in Native American Populations. The goals of this initiative are to identify key factors that contribute to avoidable mortality from specific cancers and to develop and evaluate the effectiveness of community interventions. All are randomized trials involving interventions to address the knowledge, attitudes, and screening practices of these populations. For this program, the Alaska Area Indian Health Service in Anchorage, Alaska has developed a project entitled "Prevention of Cervical Cancer in Alaskan Native Women," which targets Alaskan Native women in two locations: one urban area—Anchorage, at the Alaskan Native Medical Center, and one rural area—St. Paul Island, in the Pribilof Islands. In Anchorage, 500 women will be enrolled from a random sample of the 5,000 eligible Native residents of the area. In St. Paul, all adult women (approximately 125) are eligible to participate.

The long-term objectives of this project are to reduce the morbidity and mortality from invasive cervical cancer. The specific aims are to (1) promote knowledge and awareness of this disease, its risk factors, and appropriate screening programs and (2) enhance the existing cervical cancer screening services and follow-up care of precancerous lesions. One intervention site is a special demonstration women's health clinic that has extended evening hours, hour-long appointments, staffing by women providers and nurse practitioners, comprehensive health surveillance for women of all ages, Pap smear tracking services, individual patient education, mammography services, and tobacco cessation classes.

NCI, with the Office of Research on Women's Health, is providing support to Dr. Anne Lanier of the Alaskan Native Health Service. The purpose of this two-year study is to determine whether invasive cervical cancer in young Native Alaskan women is developing over short periods of time judging from the most recent negative screening Pap smears. From 1989 to present, 26 invasive cervical cancer cases have been identified. All lifetime Pap smears are being reviewed for the quality of the preparations and the accuracy of the diagnosis. However, it does appear in the preliminary data that young Native Alaskan women are particularly susceptible to development of invasive cervical carcinoma, suggesting that perhaps a particularly virulent virus may be prevalent in that population.

NCI and Indian Health Service (IHS) have initiated a project to collect family pedigrees of cancer cases and matched controls and to begin etiologic studies of selected malignancies, focusing initially on lymphoma, hepatocellular cancer, and cervical cancer. The latter cancer site is part of a multicenter study to investigate the role of human papilloma virus (HPV) and other cofactors in Native Americans.

NCI has also funded two Interagency Agreements with the IHS for the surveillance of the cancer burden of Alaskan Natives, and a more complex project to describe not only cancer incidence and mortality in Alaskan Natives and American Indians but also the patterns of care, risk factors, and cultural entities that form barriers to early detection and treatment. It is expected that both projects will lead to data-based intervention activities.

A new Native American Women's Cancer Initiative concept was approved in fiscal year 1993. This research will determine the effectiveness and efficacy of cancer control and prevention strategies with the following objectives: (1) address the barriers to culturally appropriate quality cancer control services including screening, appropriate follow-up, diagnosis, treatment, and rehabilitation programs for cancers that are common and/or disproportionately elevated within indigenous women, (2) reduce cancer risk behaviors in Native American women, such as high dietary fat intake, tobacco use, and alcohol consumption, and (3) assist in providing technical assistance to improve Native American women's research skills and eventually increase the number of Native American women in key research positions, such as principal investigators.

The Network for Cancer Control Research among American Indian and Alaskan Native Populations was established by NCI in 1990 to address the increased cancer incidence and mortality among American Indian and Alaskan Natives. A National Strategic Plan for Cancer Prevention and Control Research among American Indi-

ans and Alaskan Natives was developed in 1992 and presented to Department of Health and Human Services officials. In addition, a "Cancer Education Program Survey" was developed and distributed to American Indian and Alaskan Native urban and Reservation health clinics, tribal health planners, and Native health care providers to identify the types of cancer-related activities—including cervical cancer screening—in progress among American Indian and Alaskan Native peoples.

The Community Clinical Oncology Program Cooperative Agreement with the Virginia Mason Research Center in Seattle, Washington includes a component in Anchorage and an affiliate in Fairbanks, Alaska. This program provides communities that are not served by university hospitals with access to clinical treatment and prevention trials. Most notably this has provided Alaskans with the opportunity to participate in trials in the prevention of cancers of the prostate and colon as well as studies involving treatment of a number of cancers significant to this population. This program serves as a continuing medical education for health care givers and accelerates dissemination of the state of the art care technologies.

The Alaska Department of Health and Social Services receives NCI support for developing a project that will serve as a model of data use for planning and evaluating statewide cancer prevention and control interventions. Upon analysis of existing data, the two interventions that have been chosen are regional cancer data profiles and tobacco use reduction. For the first intervention, 13 separate cancer profiles will be developed. Each profile will be regionally specific as defined by the census areas/boroughs located within the boundaries of the 12 Alaskan Native Health Corporations, and the Municipality of Anchorage. Each profile will focus on all cancers, in general, and more specifically, cancers of the lung, colorectal, breast, and cervix. Information will be provided on risk factors, prevention and early detection, as well as interpretation of the findings and recommendations for cancer prevention and control.

The target audience for this intervention are the health and public policy makers within Alaska; a second distribution wave will follow for health professionals and educators. The profiles will provide the first complete review on cancer in Alaska. The expected outcome of the profiles influence is a change in the environment, specifically in local ordinances and appropriations for cancer prevention and control programs. The second intervention, tobacco use reduction, will focus on a legislative excise tax initiative accompanied by a media/grassroots campaign to increase public awareness of the harmful effects, and to decrease the social acceptability of tobacco use. If successful, the intervention is expected to have the greatest impact on youth and those with low income.

In addition to the above activities, NCI conducted a workshop entitled "Native American Training Opportunities" in August 1992 to provide information on the types of research training opportunities available in biomedical research. Topics included an overview of the peer review system and techniques for successfully applying for research grants as well as information on how to apply for fellowships. Over 100 American Indians, Alaskan Natives, Native Hawaiians, and American Samoans attended the workshop, which was designed to increase the number of Native Americans directly involved in cancer research.

A monograph entitled "Documentation of the Cancer Research Needs of American Indians and Alaskan Natives" was developed in 1993. The purpose of this publication is to provide a resource and reference to assist in the formulation of culturally acceptable cancer prevention and control research projects or programs. It is a brief overview of the cancer problem among American Indian and Alaskan Native people living in urban, rural, reservation and village sites. This publication is the first of a series of monographs that focus on Native Americans. It is designed to be used as a resource or reference to assist in the formulation of culturally appropriate cancer prevention and control research projects or programs. This monograph is primarily designed for use by Native and non-Native cancer researchers.

HELICOBACTER

Question. In addition, our Alaska Native people have the perception that the amount of cancer is increasing in their population. While I do not believe we have recent data on these issues, despite the work of Ann Lanier of the Alaska Area Native Health Service, I can conclude that part of this is true. Our efforts at health promotion and disease prevention, and our interventions that we can afford have in some measure been successful—they are living longer and therefore are experiencing more cancers that they didn't live to see in an earlier time.

The other variable has got to be smoking. The rate of lung cancer clearly bear that out, and I would appreciate your consideration of Alaska in any of your specific efforts in this area.

Gastric cancers, however, continue to be unacceptably high in western Alaska. There is some indication that this could be due to the bacteria *Helicobacter pylori*. What interventions have been tested by the National Cancer Institute in this area?

Answer. NCI has several studies underway to identify the causes of stomach cancer, including research specifically involving the bacteria *Helicobacter pylori*. NCI is also exploring chemopreventive regimens to reduce the incidence of this disease. The overall goal of this research is to gain an understanding of the etiology of stomach cancer in order to develop successful interventions that can then be applied to prevent its occurrence, particularly in those areas where it is highly prevalent.

NCI is supporting a program project grant at Louisiana State University Medical Center to study the etiology and prevention of gastric cancer. This research includes three-year controlled trials of treatments for *Helicobacter pylori* as well as dietary supplementation with ascorbic acid and beta-carotene in the prevention of gastric cancer among high-risk populations in Colombia.

In Shandong Province, a rural area of northeast China where the stomach cancer rates are among the highest in the world, NCI has been collaborating with the Beijing Institute for Cancer Research since 1983 to assess the risk factors associated with this disease and to test various means for its prevention. Initial findings showed increased risk associated with consumption of a particular local food and salt, while reduced risk was found to be related to intake of allium vegetables (e.g., scallions and garlic) and beta-carotene and vitamin C-containing fresh fruits and vegetables. In a gastroscopic screening program, chronic atrophic gastritis, an early precancerous lesion, was found in almost the entire adult population of this area. This screening program also found an association between *Helicobacter pylori* infection and the progression of chronic atrophic gastritis to more advanced states.

In collaboration with the Cancer Institute of the Chinese Academy of Medical Sciences, NCI recently reported initial results from an intervention trial in Linxian Province, a part of China with high rates for cancer of the gastric cardia (the upper segment of the stomach). Significantly reduced risks were found to be associated with dietary supplementation with beta-carotene, vitamin E and selenium. These results, among other findings, have provided the impetus for NCI to launch a multifaceted stomach cancer intervention trial in Shandong Province. Participants in the screening program will be invited to join a four-year intervention trial in which the efficacy of a number of agents will be tested. Among the measures to be evaluated are antibiotics for the treatment of *Helicobacter pylori* infection, antioxidants (i.e., beta-carotene, selenium and vitamin E), and garlic extract.

In addition, NCI is pursuing a variety of other studies to clarify the role of *Helicobacter pylori* and other possible factors in the etiology of stomach cancer.

EPSTEIN-BARR VIRUS

Question. I learned recently that the Epstein-Barr virus (EBV) is associated with nasopharyngeal cancers in Native Americans and Asian-Americans, with Burkett's lymphoma in those of African descent, and with mononucleosis in caucasians. Do we have data that would explain why, and what could explain these variables?

Answer. Epstein-Barr virus (EBV) is associated with a number of malignant and non-malignant diseases in various racial and ethnic groups. EBV is well documented as the primary cause of infectious mononucleosis, which occurs mainly in Caucasians in Western societies, and is a result of delayed infection with this virus. In most parts of the world and in lower socioeconomic groups in the United States, EBV infection usually occurs before the age of six and is not associated with any specific illness. When exposure to EBV occurs later in life, as among individuals in upper socioeconomic groups, infectious mononucleosis may occur. Thus, in the development of infectious mononucleosis, the primary factor is age at infection rather than racial or ethnic group.

EBV appears to be a necessary factor in the development of nasopharyngeal carcinoma (NPC) in all racial and ethnic groups and geographic locations. There is a higher incidence of NPC in certain Asian-Americans and in Native Americans, which seems related in part to genetic factors. Chinese populations are especially prone to NPC, with the highest rates in southern China. Dietary factors (notably salted fish) and other environmental exposures play a role along with genetic susceptibility in the development of NPC in high-risk populations. Regarding Native Americans, the elevated risk is most notable among Alaskan Natives, and NCI-supported studies are underway to clarify the role of environmental and genetic determinants. NCI is also supporting a study of nasopharyngeal cancer at Fred Hutchinson Cancer Center in Seattle, Washington. The goal of this project is to study the possible role of formaldehyde and other chemical exposures as cofactors with EBV in the development of NPC.

Burkitt's lymphoma is most common among Africans living in areas where malaria is endemic and primarily depends on the interaction of EBV and malaria. It is not more common among Americans of African descent than Caucasians, and in fact the American Burkitt's Lymphoma Registry established by NCI has documented that virtually all of U.S. cases of Burkitt's lymphoma were in Caucasians.

EBV may also play an etiologic role in some cases of Hodgkin's disease and perhaps non-Hodgkin's lymphoma in the United States, especially in individuals predisposed because of immunologic alterations. A comparative study of EBV-related Hodgkin's disease in diverse populations is now underway. Similarly, studies in EBV-associated gastric cancer in Japanese Americans and EBV-associated Burkitt's lymphoma in Ghanaians are in progress to evaluate factors determining whether EBV produces benign or malignant disease in specific populations.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF DR. CLAUDE LENFANT, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Let me go to Dr. Claude Lenfant, Director, National Heart, Lung, and Blood Institute.

Dr. LENFANT. Thank you, Mr. Chairman.

Many of the things that Dr. Broder just said, of course, apply to NHLBI and to, I guess, all of the Institutes. But I would like to take a moment to tell you about what I see that is specific perhaps to our Institute.

CARDIOLOGY RESEARCH

The research programs of our Institute are on the threshold of new, very significant opportunities. For example, if you look at cardiology research in the last 50 years, it has been very productive, as we have seen from the reduction in the death rate from cardiovascular diseases. The thrust of that research has been essentially descriptive using clinical physiology.

I think what is happening today is that we are, as I just said, on the threshold to enter the use of molecular medicine, that is, using molecular biology and cell biology, as tools to further advance our programs. These things are going to happen, there is no question.

The question is whether to do it over a very long period of time, at a very slow pace, or whether we can capitalize on all the opportunities and do it faster. Now, what is the argument to do it faster? The argument to do it faster is the following: It is that by understanding better at the molecular level the conditions with which we are concerned that we can develop new treatments, new diagnostic methods, and new preventive regimens. If we were able to couple new preventive regimens with the treatment of these conditions we would certainly continue to see a decline in death rates as we have seen in the years past and at the same time we would be able to reduce the most significant burden from these diseases, and let me explain to you why.

As I have said, the death rate of cardiovascular diseases has declined in a very significant fashion, 50 percent during the last 25 years. However, if the patients do not die, they still have the diseases. What we see as an opportunity today is to address this problem, which is to reduce the morbidity of these diseases. The fact is that we have a large number of patients with these conditions because we do not know how to prevent them.

And that is what we will be able to do by using all the approaches which I have mentioned.

So my point was to get to these opportunities as soon as possible. I cannot look at you and say if we do not have the additional money it will never happen. It will happen. The question is whether we want it to happen in, say, 20, 40 years or whether we want to reduce the time so that we can obtain the results we anticipate.

FTE REDUCTIONS

With regard to the FTE's, again what Dr. Broder has said applies to us. We see perhaps some special issues. Unfortunately, during the last 6 to 12 months we have lost a great number of our most distinguished scientists. For example, Dr. French Anderson who I have referred to in the past has left to take a university position. French Anderson is the scientist who really started gene therapy at the National Institute. He and other of his colleagues have left to take positions in universities. As yet we have not been able to recruit for these positions, to replace these people, because of the difficulties possible candidates see with our environment, and what grade they are going to get, will they be able to recruit colleagues at a grade consonant with their capabilities.

So within our intramural program we have a very significant problem that we have to address because of the FTE reduction. Also you will remember, Mr. Chairman, that last year we were given the mandate to set up the Sleep Disorder Research Center, and I have to tell you that the development of the center is certainly being slowed down; in fact we are making relatively little progress because we are hampered in our ability to start this new organization.

Clinical trials that Dr. Broder referred to are also very important to us. To conduct successful clinical trials as we have over the years takes people with competence and very high scientific qualifications.

PREPARED STATEMENT

If we cannot recruit such people, to replace those who have left in the last few months, we find ourselves in a situation where we see opportunities and needs to move forward, but yet we cannot do it because we are not going to be able to conduct programs with the quality that we would like to have.

So it is a difficult situation. As Dr. Broder said, we will do the job the best we can but the conditions are certainly very, very difficult.

Senator HARKIN. Thank you very much, Dr. Lenfant.
[The statement follows:]

STATEMENT OF DR. CLAUDE LENFANT

I am pleased to address this committee once again on behalf of the National Heart, Lung, and Blood Institute [NHLBI]. Now in its forty-sixth year, the Institute came into being at a time when elation over the public health miracle wrought by control of infectious disease was rapidly giving way to concern about the chronic diseases that stalk people as they grow older. It became apparent that enjoying a long and healthy life depended to a great extent on how well a person's heart, blood vessels, lungs, and blood functioned. That remains true today. Despite remarkable medical advances that have reduced death rates dramatically, more than half of Americans who died last year succumbed to diseases that the NHLBI is working to treat, cure, or prevent. To meet this continuing challenge, the Institute conducts a

broad-based program that emphasizes acquisition of fundamental knowledge; testing, evaluation, and validation of promising approaches derived from that knowledge; and transfer of findings to practice. The advances highlighted below attest to the success of this strategy.

The Institute supports a wide range of studies on the structure and function of the heart muscle, some of which focus on hypertrophic cardiomyopathy [HCM], an inherited heart defect that has made headlines as the cause of sudden death in apparently healthy young athletes. In a collaboration that exemplifies the benefits to be gained by close interaction between basic and clinical research, a group of NHLBI intramural investigators has integrated clinical and molecular efforts in such a way that laboratory data guide and motivate clinical research, which in turn provides material and direction for new basic studies. This research has demonstrated, for example, that use of a dual chamber pacemaker offers a therapeutic alternative to surgery that is at least as effective, less expensive, and safer for some patients. Other studies involving several hundred patients have shown that electrophysiologic [EP] tests are valuable in gauging the probable consequences of HCM in adults and children, because they enable identification of potential arrhythmic causes of sudden death and fainting spells. EP studies not only yield information on the prognosis for a given patient, but also may indicate therapeutic strategies to reduce risk.

A variety of genetic mutations can cause HCM, and are associated with different clinical characteristics and prognoses. For example, two mutations have been identified that seldom result in disease and have a benign prognosis, and a third mutation has been found to cause disease in 100 percent of affected persons and to confer a high risk of sudden death. The availability of molecular markers has made it possible to perform preclinical diagnosis of HCM in children. Thus, application of basic genetic studies to HCM and the discovery that HCM is linked to a particular gene that governs the heart muscle have transformed what was a disease defined only by its clinical manifestations into a molecular disease, and set the stage for improved clinical management and genetic counseling of patients.

The success of this approach illustrates not only benefits to be gained from the marriage of basic and clinical research, but also the exceptional promise of the discipline of molecular biology. Recognizing the vast potential of this new field, the Institute has taken a number of steps to orchestrate a program aimed at rapid yet deliberate progress.

Considerable headway is already being made with respect to cardiovascular, pulmonary, and hematologic diseases caused by a single defective gene. To guide and advance its research efforts in this area, the Institute convened a Working Group on Gene Therapy Approaches and Resources for Heart, Lung, and Blood Diseases to examine ways in which existing knowledge could be used to devise effective methods of genetic therapy for such diseases. The Working Group's recommendations have already led to development of three new programs focused, respectively, on cystic fibrosis, hemophilia, and sickle cell disease. The sickle cell initiative, which takes advantage of innovative ways of introducing modified hemoglobin genes into bone marrow cells, is expected to produce results applicable to other hereditary hemoglobinopathies such as Cooley's anemia. These efforts promise to revolutionize our mastery over diseases that have plagued generations of families.

Even more exciting is the potential application of molecular genetic approaches to multifactorial diseases, such as high blood pressure and asthma. These diseases represent a new frontier because they do not follow the classical laws of genetics and they involve special medical and societal challenges. To identify scientific priorities in this area, the Institute formed an Expert Panel on Genetic Strategies for Heart, Lung, and Blood Diseases, which recently produced a Master Plan that describes research opportunities and implementation strategies. Several new research initiatives have already been developed pursuant to this plan, including a shared support facility for mammalian genotyping and collaborative programs to delineate the major genetic determinants of high blood pressure and asthma. Although successful exploitation of this approach will demand patience, flexibility, and hard work, we believe it offers extraordinary potential for pre-symptomatic diagnosis, carrier detection, primary prevention, and cure of complex diseases. Such efforts now assume greater importance than ever in light of this country's growing interest in containing health care costs while ensuring that the benefits of modern medicine are available to all Americans.

Clinical trials are the most reliable approach to validate new knowledge and determine whether it is ready for wider application. These studies enable the Institute to assess the efficacy of therapeutic or preventive strategies; to compare outcomes among persons of various gender, racial/ethnic, or health status; and to address such issues as health quality of life and cost-effectiveness. For instance, a new clinical

trial, Antiarrhythmics Versus Implantable Defibrillators, will determine whether patients resuscitated from life-threatening arrhythmias fare better with an implantable cardiac defibrillator [ICD] or with the drugs amiodarone or sotalol. Findings will provide a valuable guide to managing patients with serious ventricular arrhythmias. Furthermore, by improving the ability to identify subgroups of patients likely to benefit from the ICD, the new information will facilitate appropriate use of this expensive new procedure. Another trial, Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack, will compare the effectiveness of four classes of antihypertensive drugs in preventing heart attacks and cardiovascular deaths in older persons. The study will enable us to distinguish differences between black and white patients, and between women and men, in their response to treatment, and to compare the effectiveness of costly newer drugs, such as ACE inhibitors, with that of inexpensive older drugs, such as diuretics.

The NHLBI currently supports five major technology transfer activities: the National High Blood Pressure Education Program, the National Cholesterol Education Program, the National Asthma Education and Prevention Program, the National Heart Attack Alert Program, and the Obesity Education Initiative. Although these programs consume only a small fraction of the Institute's budget, they are among its most important efforts because they play such a visible role in bridging the gap between fundamental research findings and health-related behavior. Their influence ranges from updating standard medical practices in the United States to changing the everyday habits of its citizens. Not only do they facilitate the most effective application of NHLBI research findings, but they also identify new research directions that demand exploration.

During the past year, the National Asthma Education and Prevention Program [NAEPP] developed a broad-based strategy with respect to asthma prevention, focused on persons, especially minorities, with undiagnosed asthma. A mass media campaign has been implemented nationally to create greater awareness of asthma's warning signs and to encourage people who experience them to seek treatment. Reducing the burden of asthma in young children is the goal of several new school-based initiatives. "Asthma Awareness: A Curriculum for the Elementary School Classroom" and a videotape for teachers on managing asthma are being distributed widely to help both teachers and students learn about how they can help schoolchildren with asthma. The National School Boards Association and the NAEPP are developing a joint policy statement that will encourage schools to assure convenient and prompt access to asthma medications, and give appropriate consideration to student self-administration. A new NHLBI research initiative, "Interventions to Improve Asthma Management and Prevention at School," will develop and evaluate innovative programs that incorporate all components of a comprehensive school health program. Applications from schools that serve minority populations will be encouraged, given the greater severity of asthma and the higher risks for school failure among minority children.

As the country moves forward with health care reform, we believe the spectrum of activities conducted by the NHLBI will expand the range of choices open to policymakers and facilitate achievement of the nation's public health objectives.

Mr. Chairman, the fiscal year 1995 NHLBI budget request, excluding the amount for AIDS related research, is \$1,266,961,000. I would be pleased to answer any questions the committee may have.

BIOGRAPHICAL SKETCH OF DR. CLAUDE LENFANT

Born: October 12, 1928, Paris, France.

Education: B.S., University of Rennes, France, 1948; M.D., University of Paris, France, 1956.

Professional history: 1957-58, Research Fellow, University of Buffalo, New York; 1958-59, Research Fellow, Columbia University, New York; 1959-60, Assistant Professor of Physiology, University of Lille, France; 1961-65, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle; 1966-67, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle; 1968-71, Associate Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle; 1970-72, Acting Associate Director, Collaborative R&D Program, National Heart and Lung Institute, NIH; 1970-72, Associate Director for Lung Programs, National Heart and Lung Institute, NIH; 1971-72, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle; 1972-80, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH; 1981-82, Associate Director for International Research, NIH; 1981-82, Director, Fogarty International Center for Advanced Study

in the Health Sciences, NIH; 1982–Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional organizations: Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Federation for Clinical Research, French Physiological Society, International Federation for Medical Electronics, American Society of Zoologists, Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Science.

Honors and awards: Thesis Prize, University of Paris, France, 1956; Commendation Tohoku Medical Society, Sendai, Japan, 1973; Superior Service Honor Award, DHHS, 1974; Regents' Professor, University of California, Los Angeles, 1975; Testimonial Dinner, American Thoracic Society, 1979; Honorary Fellow, American College of Chest Physicians, 1979; Honorary Professor, National Yang-Ming Medical College Taipei, Taiwan, 1980; Honorary Professor, Universidad Peruana Cayetano Heredia, Lima, Peru, 1981; Senior Executive Service Performance Award, 1982; Elected Institute of Medicine, National Academy of Sciences, 1983; American Heart Association Scientific Councils' "Distinguished Achievement Award," 1983; Senior Executive Service Performance Award, 1983; Honorary Fellow Council on Clinical Cardiology—American Heart Association, 1984; Senior Executive Service Performance Award, 1984; Forrest M. Bird Contributory Award, American Respiratory Therapy Foundation, 1985; Senior Executive Service Performance Award, 1985; Presidential Meritorious Executive Rank Award, 1987; Elected Honorary member, Royal Society of Medicine, England, 1988; Honorary Doctor of Science, State University of New York, Buffalo, 1988; Elected member USSR Academy of Medical Sciences, 1988; Cystic Fibrosis Foundation "Breath of Life" Award, 1988; Elected Honorary Member—French Cardiology Society, 1989; Senior Executive Service Performance Award, 1989; Brotherhood Award—Association of Black Cardiologists, 1990; Appointed, Board of Governors, U.S.-Israel Binational Science Foundation; 1990–93, Senior Executive Service Performance Award, 1990; Presidential Distinguished Executive Rank Award, 1991; Elected Fellow, Royal College of Physicians (London, England), 1992; Senior Executive Service Performance Award, 1992; 1992 Federal Executive of the Year Award; Elected member, French National Academy of Medicine, 1993; Surgeon General's Exemplary Award, 1993; Senior Executive Service Performance Award, 1993; Special Recognition Award—American Academy of Allergy and Immunology, 1994.

Authorship, editorship: Author or Co-Author of 200 scientific publications Served on Editorial Boards of: *Am. Journal of Physiology*; *Journal of Applied Physiology*; *Respiratory Physiology*; *Am. Review of Respiratory Disease*; *Undersea Biomedical Research*; *Proceedings of Society for Experimental Biology and Medicine*; *Revue Francaise des Maladies Respiratoires*; *Journal of Applied Physiology*; *Respiration, Environmental and Exercise Physiology*; *Am. Journal of Medicine*; Continuing Education for Family Physicians; Executive Editor of 74 volumes for monograph series, "Lung Biology in Health and Disease."

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CYSTIC FIBROSIS

Question. The first successful gene transfer for cystic fibrosis has recently been reported. Please describe this development and what it means for patients with CF.

Answer. This development is a very significant one. In the experiment conducted within our intramural program at the NIH Clinical Center, 4 patients had normal genes transferred to the airway epithelium using a viral vector. The patients were three men and one woman, ages 23 to 25 years. One patient had an inflammatory response so the data were reviewed, and a decision was made to resume the protocol using a lower dose. All the patients are fine and are clinically stable.

The protocol is not designed to bring about clinical change in the patient. Rather, this study will provide information on safe dosage levels, the extent to which expression of healthy genes in the lungs occur, and whether genes can be transferred on

a repetitive basis without the body developing resistance and without inflammatory side effects.

This research is in its early stages. It will be several years before larger clinical trials are possible. However, even if the technique is not feasible for cystic fibrosis, it may have therapeutic utility for other diseases where repetitive doses are not needed.

The Institute also supports extramural research on gene therapy for cystic fibrosis with a similar focus. In time, this promising research may lead to an effective therapy for cystic fibrosis patients.

BEHAVIORAL RESEARCH

Question. The fiscal 1994 Senate Committee report encouraged NHLBI to "redouble its efforts" to examine the role of biobehavioral factors in the course of coronary heart disease. That report also mentioned that none of the existing NHLBI specialized centers of research (or SCOR) are behaviorally focused. Dr. Lenfant, describe your Institute's work in the area of behavioral research and heart disease.

Answer. The National Heart, Lung, and Blood Institute continues to place a high priority on behavioral research. NHLBI funding in this area over the last five years has increased 113 percent, compared to an increase of 16.1 percent for the total Institute budget. In fiscal year 1994, the Institute is considering new programs expected to have a substantial impact on progress in the area of health and behavior with respect to coronary heart disease. One of these focuses on biobehavioral mechanisms of essential hypertension in women and men under age 40 and would determine whether a systematic difference, by race or gender, exists in neuroendocrine and physiologic responses to psychosocial stress. Another program would support research on enhancing recovery in coronary heart disease patients by determining the effects of psychosocial interventions on morbidity and mortality.

In addition to these new initiatives, the Institute supports a number of ongoing behavioral studies. Examples of research currently supported by the Institute are:

The Raynaud's treatment study.—This randomized, multi-center trial uses behavioral interventions (biofeedback) for Raynaud's disease, a painful condition which affects blood flow in the extremities, and can be disabling. About two-thirds of all cases occur in women. The study is unusual in that multi-center clinical trials of behavioral interventions have rarely been conducted for any somatic illness.

Psychophysiological investigations of myocardial ischemia.—This major, multi-center study is investigating the psychological, neurological, and physiological factors that cause the symptoms of myocardial ischemia. The three aspects have been studied separately, but never in such an integrated, comprehensive way. From this study, we expect to have a much better understanding of asymptomatic myocardial ischemia.

Health quality of life.—The Institute is a leader in quality of life research, and is continuing its policy of including quality of life in all its clinical trials. One good example is the comprehensive Post-Coronary Artery Bypass Graft biobehavioral study involving more than 750 patients. From this study, we expect to improve our knowledge of what contributes to full restoration of function, including return to work, in bypass patients. Other clinical trials in which quality of life is playing an important role include the Childhood Asthma Management Program, Multi-Center Study of Hydroxyurea in Sickle Cell Patients, and Postmenopausal Estrogen/Progestin Interventions Study.

Adherence to treatment in clinical trials.—The Institute recently launched a new effort to understand how to improve patients' adherence to their treatments in clinical trials. The study will contribute to better clinical trials, and has potential benefits for standard clinical care of patients with heart and lung diseases.

Cystic fibrosis.—The NHLBI is developing methods for improved self-management by cystic fibrosis patients. It is expected that the methods will contribute to improved health outcomes and result in better psychological adjustment of cystic fibrosis patients.

Program projects.—The Institute currently supports four major program project grants in behavioral medicine. They include studies of cardiovascular reactivity; of psychosocial factors, anger, and hostility in coronary heart disease; and behavioral factors and stress in borderline hypertension.

SLEEP CENTER

Question. What is the status of the National Center on Sleep Disorders Research, and what are its principal objectives?

Answer. The National Center on Sleep Disorders Research is becoming a reality. The materials required to establish the Center as an organizational unit are at the

Office of the Secretary. Nominees to the Sleep Disorders Research Advisory Board have been invited to serve. The first Advisory Board meeting, which is scheduled for June, will focus on developing the National Plan for Sleep and Sleep Disorders Research. In addition, the Advisory Board will help develop a strategy for a national education program related to sleep disorders.

The principal objectives of the Center are to direct and sponsor research, training, dissemination of health information, and other activities related to sleep and sleep disorders; conduct and support evaluations and assessments of national and international sleep disorders research; prepare a comprehensive national plan for research on sleep disorders and work to facilitate its implementation; and coordinate the activities of the Center with similar activities of other Federal Agencies and other components of the National Institutes of Health. The Center will serve four key functions: coordination; support of crosscutting basic and clinical research; training of scientists; and education and technology transfer to health professionals, policymakers, patients, and the public.

QUESTIONS SUBMITTED BY SENATOR HATFIELD

NATIONAL CENTER ON SLEEP DISORDERS RESEARCH

Question. Dr. Lenfant, I am hopeful that the Center for Sleep Disorders Research will provide leadership across the federal government to coordinate research and public education efforts on the problems and consequences of sleep disorders. Do you envision collaborative efforts with other agencies? If so, could you describe some of these and how quickly you anticipate getting them underway?

Answer. Yes, the National Center on Sleep Disorders Research [NCSDR] has already initiated some collaborations with other agencies and anticipates more in the future. For example, the NCSDR is currently working with NASA to develop joint programs in sleep, prolonged shift work, human performance, sleep loss and fatigue both on earth and in the microgravity environment. A recent NHLBI/NASA workshop identified a number of promising short and long term directions, which would be relevant to the mission of both agencies. We anticipate implementing a joint initiative in this area in fiscal year 1995.

The NCSDR will conduct a strategy development workshop in June 1994 to plan for a national sleep education program. The workshop will include representatives from the Departments of Transportation, Defense, Veterans Affairs, Commerce, Labor; Centers for Disease Control and Prevention; and the National Aeronautics and Space Administration. The workshop will provide recommendations for both public and professional education. We are hopeful that other federal agencies, and professional and voluntary organizations, in cooperation with the NCSDR will begin to implement some of the recommendations beginning in fiscal year 1995. The NCSDR is also working with the Federal Highway Administration to assist with the scientific and technical review of a proposal to examine the incidence of sleep apnea in drivers of commercial motor vehicle carriers. We anticipate that this will be the start of joint research and education activities related to sleepiness, fatigue, and sleep disorders as they relate to traffic accidents.

Lastly, the Director, NIH, has recently appointed members and ex officio representatives to the Sleep Disorders Research Advisory Board. The Board, along with ex officio members from a number of federal agencies, will assist the NCSDR in identifying research priorities and developing plans for coordinating sleep and sleep disorders research across the federal government and with other private organizations. The first meeting of the Board will be in the summer of 1994.

Question. What initiatives will the Center support in fiscal year 1995?

Answer. The Center is considering a number of initiatives and would implement one or two from the following list depending upon availability of resources. The first is a basic science initiative on the cellular and molecular basis of sleepiness. The goals would be to understand the fundamental neurobiological mechanisms of sleep homeostasis, circadian rhythms, and sleep deprivation. It would answer questions related to the basic function of sleep and brain activity during the different states of sleep; the neurobiologic mechanisms by which sleep is regulated and controlled; and the genetic expression of sleep neuromodulators, peptides, and mediators during normal sleep and in sleep apnea. The second is a clinical initiative on the role of pharmacological agents compared to behavioral interventions for persistent insomnia. This program would also investigate the physiological mechanisms that may account for the potential link between poor sleep, insomnia, and cardiovascular disease and whether insomnia may be predictive for future cardiovascular events. A third initiative would focus on the neural and immunologic mechanisms of nocturnal

asthma. The goals would be to investigate the pathophysiologic/immunologic mechanisms of nocturnal asthma, with specific emphasis on understanding circadian aspects of physiology, bronchial reactivity and inflammation. The fourth one is on sleep and recovery in the critical care patient. The goals of this initiative would be to assess the factors responsible for sleep deprivation in the critical care patient, and to develop interventions to minimize sleep disturbance and sleep deprivation in patients recovering from illness or surgery in the critical care setting. Lastly, based on the recommendations from the strategy development workshop, the Center will consider a health education initiative to inform health care professionals about sleep and sleep disorders. The development of treatment guidelines to assist primary care physicians and health care providers on how to recognize and manage patients with sleep disorders could possibly be initiated in fiscal year 1995.

Question. Would you provide the Committee with your funding estimates for the Center for fiscal year 1994 and fiscal year 1995?

Answer. The NHLBI estimate for sleep disorders research is \$13,300,000 in fiscal year 1994 and \$17,300,000 in fiscal year 1995.

RED WINE AND CORONARY HEART DISEASE

Question. Dr. Lenfant, I understand that two recent analyses of the 1988 National Health Interview Survey by Lewin-VHI indicate that moderate wine consumption may be protective against heart disease. Lewin-VHI contend that significant health care cost savings, and a reduction in hospitalization and deaths from heart disease, could be realized if more adults were to consume moderate amounts of wine. Would you comment on these findings?

Answer. The study you refer to is an epidemiologic study that indicates an association of variables with disease outcomes but cannot prove causality. Other variables such as differences in diet, genetics, or physical activity, for example, may confound the analysis.

Question. Have you considered updating this 1988 study to further detail the potential health benefits from wine consumption?

Answer. The NHLBI does not have any plans to update this study. However, other studies in this area are supported by the Institute.

Question. Is there additional research in this area?

Answer. A number of other studies have suggested possible mechanisms of protection from heart disease by substances which are in red wine and not in white wine, and which may act as antioxidants and thereby possibly slow down the atherosclerosis occurring in coronary arteries. Certain substances in wine may reduce clotting tendencies which may prevent some heart attacks from occurring.

Several epidemiologic studies, but not all, demonstrate proportionately more deaths among abstainers and in heavy drinkers and fewer deaths among moderate drinkers. There have also been a number of studies which show that moderate intake of alcoholic beverages increases the high density lipoprotein cholesterol, that appears to be protective against heart attacks ("the good cholesterol"). However, as you well know, too much alcoholic intake increases accidents, elevates blood pressure, causes dysfunction of the heart muscle, and increases strokes, liver disease, pancreatic disease, and possibly certain cancers. In some people, because of their metabolism, the negative effects outweigh the positive effects at modest levels of alcohol intake.

Question. Is the research sufficient to merit undertaking initiatives to educate physicians and consumers about the health effects of moderate wine consumption?

Answer. Additional research is needed before any national educational program can be designed that would be assuredly beneficial. Epidemiologic studies and basic science and clinical studies of mechanisms are continuing.

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF DR. HARALD LÖE, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Welcome back again.

Dr. Löe is the Director of the National Institute of Dental Research, and you will be leaving?

Dr. LÖE. That is correct; I will be leaving the Institute in early June after almost 12 years with NIH.

IMPACT OF BUDGET INCREASE AND FTE SITUATION

I would like to respond to your first question by saying that we have been very successful in preventing oral disease, especially in children and young adults; that success is now moving up to include those in midlife—about 40 years of age.

We have seen tremendous improvement in oral health in this country. On that basis, and the fluoride story that Dr. Varmus mentioned, we are now taking advantage of an extraordinary opportunity in molecular biology, and to applying this to the mouth and the oral diseases.

Just to give you one example, in the last year, we introduced new genes in the salivary glands, specific genes which express proteins that will prevent yeast from growing in the mouth. This is a very specific use of gene technology, and there are enormous possibilities in terms of designing specific defense mechanisms for controlling oral disease.

With the increased funding you have suggested, we could go full force in applying these opportunities to oral diseases. Although we have come a long way, we need more research on craniofacial development, and developmental anomalies such as cleft lip and cleft palate. Many of these are genetically guided and governed. We have at this point mapped about 1,000 of the genes that might be important in terms of the development of the face, the jaws, and the teeth.

Regarding the FTE situation, the reductions mean that we are not really able to maximize our effort. If we had more people and more money, we would go faster and would do more, particularly in molecular epidemiology, where we are applying molecular technology to demographic studies.

SCIENTIFIC OPPORTUNITIES

We have major family studies available that would enable us to get on with the understanding of genetic and environmental factors that relate to developmental anomalies and to other oral diseases that are genetically governed. In the whole area of molecular tech-

nology and molecular biology, we would very much like to expand and maximize these opportunities.

Because we have been so successful in the prevention and control of tooth decay and periodontal disease, people are retaining more and more teeth. Our goal is for Americans to maintain their natural teeth for their lifetime. We are well on our way.

But there are still risk groups in this Nation that do not seem to benefit as much from general preventive measures as others do, for both socioeconomic and biological reasons. The expansion of our research efforts in the oral disease area has evolved from our attempts to include the systemic diseases that afflict the oral cavity, and there are several of them.

There is probably no better example than diabetes, which has tremendous impact on periodontal disease and retention of the teeth.

Another very prominent systemic condition is Sjögren's syndrome. These patients have no tears and no saliva, and it is a miserable condition, of course. We all have had a dry mouth on occasion, but to have a permanently dry mouth is an absolutely incredible way to spend a life.

We can deal with these patients today. One of the research efforts that we have going is to try to introduce genes into the salivary glands that will produce fluid and electrolytes—sodium, potassium, or whatever else is needed.

PREPARED STATEMENT

So here we are at the frontiers of new scientific opportunity; there is so much we want to do. Risk group identifications with disease markers and new developments in the molecular area on the horizon would be pursued full force if we had a 50-percent increase in the budget.

[The statement follows:]

STATEMENT OF THE DR. HARALD LÖE

NIDR began the nineties with a Long-Range Research Plan that emphasized three major goals: to work toward the eradication of dental caries and periodontal diseases, to maintain the natural teeth for the lifetime, and to expand our research to address all the problems that affect the teeth, the mouth, the face, and the jaws. To achieve these goals we pledged our commitment to individuals and groups at highest risk for oral diseases and craniofacial disorders. These groups include many older Americans and "special care" patients: people whose oral health is compromised by disability or by systemic disease and systemic disease treatments, including people with AIDS, genetic diseases, and chronic conditions such as diabetes and arthritis, and the many people on multiple medications.

With respect to special care patients, NIDR is pursuing several recent advances on many fronts, ranging from the discoveries of the genes responsible for a number of hereditary diseases of teeth and bones, to promising new research on a salivary inhibitory factor against the AIDS virus, to new findings with regard to systemic diseases that affect oral health, and to new insights into conditions more common in aging, such as oral cancer.

Oral cancer research is benefitting greatly from the discovery of biomarkers associated with tumor growth or tumor suppression. These include the so-called cancer genes (proto-oncogenes) as well as tumor-suppressing genes, along with cell factors such as stress proteins, growth factors, and enzymes related to the spread of cancer. These studies have provided the rationale for the use of beta-carotene and vitamin E to reduce the risk of premalignant oral lesions from developing into frank oral cancer. Our scientists are now testing which markers may be the most useful and reliable in order to enhance the effectiveness of clinical trials of chemopreventive drugs. We are collaborating with the National Cancer Cancer Institute in two studies: one

involves an evaluation of treatments of oral cancer in elderly patients; the second is a study of risk factors comparing a patient and control population in Puerto Rico, where the prevalence of oral cancer is high.

Many members of ethnic and racial minorities are at high risk for oral disease. Not only is their oral health generally poorer than that of the white majority, but they often lack access to care. To address these problems, the Institute is currently supporting six developmental grants for Regional Research Centers for Minority Oral Health. These centers involve minority dental schools or schools serving large minority populations in San Antonio, Washington, New York, Newark, Nashville, and Los Angeles. Now in their third year, the centers have launched a number of studies, including looking at lifestyle in relation to oral health; oral manifestations of HIV infection in minority groups; oral cancer (which affects blacks disproportionately); and the relationship between periodontal disease and diabetes among Hispanic populations. The developmental grants will be replaced by full-scale, 5-year research center awards in fiscal year 1995.

It is of some interest that a number of the systemic diseases that reflect on the well-being of the oral cavity are more prominent in women than in men. Sjögren's syndrome, in which the salivary and tear glands are progressively destroyed, affects nine times as many women as men. The need to find better treatments for this devastating disorder has led to testing combinations of drugs: an agent to stimulate gland secretion, and a drug to decrease the autoimmune response. Our long-term goal is to understand how and why the glands are destroyed. Our efforts in fiscal year 1995 will focus on certain immune cells that produce substances called cytokines, which have multiple effects on other cells. It now appears that one cytokine, interferon gamma, can stop salivary cell growth during turnover. Understanding that process could lead to the development of drugs to block glandular destruction and thus provide relief to thousands of affected patients.

Many bone and joint diseases are also more prevalent in women, including osteoporosis, rheumatoid arthritis, and temporomandibular disorders (TMD's), conditions of pain and dysfunction in and around the jaw joint. In order to capitalize on the expertise at NIDR and other NIH components, the Institute has proposed that a multi-institute hard tissue disorders clinic be established at the NIH Clinical Center in fiscal year 1995. This would create, for the first time at the NIH, a clinical research site where patients with debilitating, painful conditions of cartilage and bone could be studied.

NIDR is committed to furthering research on the temporomandibular disorders [TMD's], which women report twice as often as men. In some cases individuals have undergone surgery to place a joint implant—or to remove the implant in cases where it has failed. The Institute has long advocated conservative approaches aimed at restoring function and relieving pain, and will continue to support basic research to understand the causes and natural history of TMD's. One important result of this research has been the development of new research diagnostic criteria, using both physiological and psychological measures. Ultimately, using these criteria, investigators can effectively study surgical and non-surgical interventions.

We are also supporting several new initiatives to stimulate an expansion of TMD research. Principal among them is an International Workshop on the Temporomandibular Disorders and Related Pain Conditions scheduled for April 1994. This meeting, co-sponsored by the Office of Research on Women's Health, other NIH components, the Agency for Health Care Policy and Research, and the Food and Drug Administration, will bring together a world-class group of investigators to delineate the state of the science and develop a research agenda. Representatives from TMD patient groups will also attend. These efforts and the expanded research agenda for fiscal year 1995 are expected to yield improved patient and provider guidelines for the diagnosis, treatment, and prevention of TMD's.

At the basic research level, our scientists have noted a connection between female hormones and inflammation. Women suffer more inflammatory diseases than men, and these conditions are often worsened during pregnancy (e.g., the swollen, inflamed gums of pregnancy gingivitis and exacerbations of autoimmune diseases such as lupus). Now our investigators have evidence that the hormones, estrogen and progesterone, but not the male hormone, testosterone, increase the adhesion of white blood cells to the cells that line blood vessels. This is a critical step in the cascade of events that leads to the tissue swelling, redness, and pain of inflammation. Future studies to be supported within the fiscal year 1995 budget will be aimed at understanding the ways that female hormones modulate the immune system and developing ways to counter unwanted effects.

In January of this year the Institute launched the National Oral Health Information Clearinghouse as a resource to aid the special care community. Patients and their families need information about their condition; practitioners can contact the

Clearinghouse for comprehensive information to better serve these patients. Clearinghouse services include maintaining a reference database of all oral health information publications and materials, and producing and distributing patient and provider education materials. The service is accessible by computer, letter and telephone.

The transfer of research advances to the public and profession has been further advanced by a series of continuing education programs for dental practitioners, the most recent of which was held in Seattle in March 1994. We have included in these presentations a discussion of a new approach to the treatment of tooth decay. The new concept emphasizes caries as a bacterial disease—one that can be eliminated in its incipient stages by eradicating the bacteria and adopting sound dietary and self-care habits, including the use of remineralizing solutions—instead of considering caries merely in terms of a cavity to be filled. If a filling is necessary, we emphasize materials and methods that minimize the loss of tooth substance.

This new emphasis parallels major efforts to develop new and improved biomaterials. In part, this research has been stimulated by concerns raised about the possible toxicity of the mercury contained in the standard dental amalgam. While there is no scientific evidence that the amount of mercury used in fillings is harmful, NIDR-supported research has led to the development of a mercury-free dental filling. The metals are consolidated using processes called fast diffusion and cold welding, where the bulk of the consolidation occurs when the filling is placed. A Cooperative Research and Development Agreement has been negotiated with industry to commercialize the technology, and we expect to start clinical trials shortly.

Mr. Chairman, at the outset I mentioned the NIDR Long-Range Research Plan. I did not mention its title, but from what I have described, I believe we were justified in calling the Plan, *Broadening the Scope*.

The fiscal year 1995 budget request for the National Institute of Dental Research is \$163,776,000. I would be pleased to answer any questions.

Birthplace and date: July 19, 1926, Steinkjer, Norway.

Citizenship: USA.

Education: Oslo University, Norway, D.D.S., 1952; Dr. Odont, 1961.

Professional history: 1974–82, Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington; 1972–74, Director of the Dental Research Institute and Professor of Dentistry, University of Michigan, Ann Arbor; 1962–72, Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus; 1971–72, Associate Dean and Dean-elect, Royal Dental College, Aarhus; 1966–67, Visiting Professor of Periodontics, Hebrew University, Jerusalem; 1956–62, Research Associate, Norwegian Institute for Dental Research, Oslo; 1960–62, Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Oslo; 1959–62, University Research Fellow, Oslo University, Oslo; 1957–58, Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago; 1952–55, Instructor in Operative Dentistry, School of Dentistry, Oslo University, Oslo.

Honorary doctorate degrees: University of the Pacific, 1993; University of Helsinki, 1992; University of Detroit, 1990; Medical University of South Carolina, 1990; University of Toronto, 1989; Royal Dental College, Copenhagen, 1988; Honorary Professorship, Medical Sciences University of Beijing, 1987; University of Medicine and Dentistry of New Jersey, 1987; University of Maryland, 1986; University of Bergen, Norway, 1985; Georgetown University School of Dentistry, Washington, D.C., 1983; University of Lund, Sweden, 1983; Catholic University of Leuven, Belgium, 1980; University of Athens, Greece, 1980; Royal Dental College, Aarhus, Denmark, 1980; University of Gothenburg, Sweden, 1973.

Senator HARKIN. I appreciate that. I never thought about genetic research having anything to do with dental research. I guess I never thought about that.

Dr. LÖE. If I may have one more moment, I want to thank you for your support of this Institute over the years. You and other members of this committee have been very important, not only to

NIDR but to the extramural community in the universities and to the public. We have made tremendous progress.

Senator HARKIN. I appreciate that very much. I respond in kind by thanking you for your many years of service, Dr. Loe. I wish you the best.

Dr. LOE. Thank you.

Senator HARKIN. Where are you headed?

Dr. LOE. I am going back to the university for a while and see life there. I came from the university; I am going back.

Senator HARKIN. Very good. Thank you again for your years of service.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

PREVENTION RESEARCH

Question. NIDR has long emphasized research leading to disease prevention. What new prevention efforts are planned or underway at your Institute?

Answer. One of the most exciting developments in prevention this year has been the demonstration that we can put genes into the salivary glands that will express proteins which in turn protect the mouth against infection. In animal studies, NIDR staff scientists placed a gene for an anti-fungal protein into the salivary glands, and the protein was secreted in saliva. This development offers the hope of preventing candidiasis—a serious problem in immuno-suppressed and AIDS patients. Other important activities include:

- Establishment of a new intramural laboratory of molecular epidemiology and disease indicators aimed at identifying the genes and risk factors for craniofacial birth defects and oral cancer. The goal of this laboratory as well as a number of our grantees is to develop biomarkers of disease or risk factors for disease using easily sampled saliva or other oral tissues.
- Continuing research on genetically engineered vaccines and other immune approaches to prevent dental caries, certain forms of periodontal disease, and oral herpes simplex virus infections.
- Plans to pursue efforts to increase the use of dental sealants to prevent decay on the chewing surfaces of teeth.

Many of our prevention efforts are targeted to populations at greatest risk for oral diseases and disorders, including racial and ethnic minorities. In this regard we are currently supporting six developmental Regional Centers for Minority Oral Health in San Antonio, Los Angeles, Washington, Nashville, Newark, and New York. In San Antonio, for example, our researchers are evaluating the use of inexpensive laboratory tests to determine the risk for periodontal disease in Mexican-American mother-daughter pairs; they are also conducting a program to improve dietary control in diabetic patients to see if salivary flow will increase, and the risk for periodontal disease be reduced. In our minority center in Newark, investigators are determining which black children are at highest risk for tooth decay, prior to mounting a major prevention program. In other centers our grantees are studying the risk for a severe form of periodontal disease more common in black adolescents; looking for biomarkers for cleft lip and palate; and studying why oral cancers are more prevalent in blacks and Hispanics. We also have grantees who are conducting clinical trials of agents to prevent progression of oral lesions to full-blown cancer.

Older Americans and people with systemic diseases and disabilities are also at high risk. Some examples of ongoing studies include:

- Testing the use of fluoride to prevent root caries;
- Comparing different strategies to prevent gingivitis and tooth decay in elderly patients who attend public health department dental clinics;
- Identifying risk factors for tooth loss;

- Testing whether daily use of antibacterials will prevent recurrence of periodontal disease in Pima Indians—where the prevalence of adult diabetes is the highest in the world;
- Exploring whether oral bone loss can predict the risk of osteoporosis;
- Aiding patients with Sjögren's syndrome (in which the salivary and tear glands are progressively destroyed) and others who experience dry mouth or are at high risk for tooth decay by developing artificial salivas and other fluids to provide protection to the oral tissues and supply the minerals necessary to maintain the teeth.

CENTERS FOR AGING RESEARCH

Question. NIDR currently supports two centers on oral health in aging in Iowa and Texas. Describe the research being done at these centers and detail how this research benefits our oldest citizens and those with disabilities?

Answer. Our grantees at Iowa are experts in the field of oral soft tissues—the so-called oral mucosae. Their focus in the center will be on mucosal infections caused by viruses or yeasts, and on oral cancer, which is more prevalent in older-aged groups. They will be looking at the possible association of oral cancer with infection by the human papillomavirus as well as studying the role of certain enzymes, so-called anti-oxidants, in the treatment of oral cancers. These studies may well have applications to other cancers or diseases of aging. One theory of aging suggests that as we grow old our cells accumulate extremely reactive oxygen molecules that can harm DNA and other cell molecules. Anti-oxidants scavenge these molecules and could thus prevent their destructive effects.

The center in San Antonio will study aging in Mexican-American and non-Hispanic white middle-aged and older populations of men and women. The investigators' studies will include research on how aging affects the muscles and joints we use in eating and whether age-related changes in function have adverse effects on oral health. Similar studies will determine if there are age-related changes in the salivary glands, saliva, and tooth pulp. Overall, the intent of this center will be to explore how oral health is affected by the aging process in populations with different lifestyles, different disabilities, or frequencies of disease such as diabetes (higher in Mexican Americans), and how oral health status affects the quality of life. Significantly, the research underscores what we in dentistry have always known: the mouth is connected to the rest of the body and if you don't have oral health you're not healthy.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY
DISEASES

STATEMENT OF PHILLIP GORDEN, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Phillip Gorden, Director of the National Institute of Diabetes and Digestive and Kidney Diseases.

Dr. GORDEN. Thank you, Mr. Chairman. I would certainly be pleased to provide for the record some of the numbers that you have requested, but I would prefer to give an example of what you are referring to.

DIABETES CONTROL AND COMPLICATIONS TRIAL

Dr. Varmus referred to the diabetes control and complications trial which has just been completed by NIDDK, a long trial which has had a very dramatic result in terms of demonstrating that control of blood sugar can prevent or at least delay the complications of diabetes. This is a study that will have enormous impact on clinical care.

In addition, a second study has to do with a drug called an ACE inhibitor that will actually ameliorate the course of end-stage renal disease once the diabetic has begun to slip into it.

Now, the point is that we have learned that these complications are related to the intensity and the duration of blood sugar outlay. It is imperative then that we address this by a very broad initiative. We must address it by a prevention initiative with respect to the cause of the disease, both non-insulin-dependent and insulin-dependent diabetes, and that goes back to very basic research involving the multigenic causes of the disease and the immunologic deficiencies related to it. Those have to be addressed.

We then have to learn all the sequence from the inciting cause to the major manifestations of the disease. We are learning that very rapidly, because each time we learn a key point in the course of the disease it gives us another point of intervention, another point for interdiction of the disease.

PREPARED STATEMENT

We have learned that a drug that we had no idea would have any effect on renal functions has an effect on control of blood to the kidney, and that has a major effect on the rate at which the kidney deteriorates once it has been insulted by this longstanding disease. That drug was developed by a rational process, by understanding the enzymes that are related to the special agents that affect cell communication. Now we must clearly use this information to help prevent diabetic complications.

[The statement follows:]

STATEMENT OF DR. PHILLIP GORDEN

I am pleased to highlight the research progress and plans of the NIDDK in combating many of the Nation's most serious, chronic and costly health problems, including: diabetes and metabolic diseases; digestive diseases; kidney and blood disorders; and urologic disorders. Uniting these clinical areas is a solid foundation of basic research on the nutrition sciences, endocrinology, molecular genetics, immunology, virology and other fields.

The NIDDK is strongly committed to research on both insulin-dependent and non-insulin dependent diabetes, which affect an estimated 14 million Americans at an annual cost of over \$90 billion. Both forms of the disease are insidious, with long-term complications that include blindness, nerve damage, limb amputations, kidney failure and heart disease.

Two of our most recent research advances have enormous implications for improved clinical management of diabetic complications. First, the multicenter NIDDK "Diabetes Control and Complications Trial," concluded that complications damaging the small blood vessels can be prevented or delayed in insulin-dependent diabetes. The key is to maintain blood glucose levels as close to normal as possible. In this ten-year study involving over 1,400 people, intensive therapy reduced by 76 percent the risk for developing diabetic eye disease, and greatly delayed the onset and slowed the progression of kidney and nerve damage. A second prevention landmark is the discovery that the blood-pressure lowering drug captopril has a beneficial effect on the kidney disease of insulin-dependent diabetes. Results of this clinical trial were dramatic: a 50 percent reduction in the combined risk of death, dialysis or transplantation. In February, FDA approved captopril for diabetic kidney disease. This treatment could save an estimated \$2.6 billion in dialysis costs over 10 years.

In parallel with the fight against diabetic complications, we are continuing vigorous research to understand and prevent the onset of diabetes itself. In highly promising basic studies, scientists have found that injection of an enzyme called GAD prevented the development of insulin-dependent diabetes in mice prone to this disease. This research suggests that GAD may have therapeutic potential in susceptible children and young adults. Basic research in experimental animals forms the basis of a new clinical trial to assess whether prophylactic use of low-dose intravenous or oral insulin can prevent or delay the onset of insulin-dependent diabetes in individuals who have both biologic markers and family histories predictive of the disease. In non-insulin-dependent diabetes, which disproportionately affects our minority populations, an exciting new NIDDK initiative is a full-scale randomized clinical trial aimed at preventing or delaying disease onset. This study derives from basic studies in experimental animals and patients that have delineated a focus for this preventive strategy. A cornerstone of our efforts to prevent the onset of both forms of diabetes is the search for disease-causing genes. We are making progress in identifying candidate genes and in harnessing broad scientific expertise through our Diabetes Interdisciplinary Research Programs and Research Centers Programs.

Prevention is also a theme of our research on digestive diseases, including ulcers, inflammatory bowel disease and liver disease. A recent NIH Consensus Development Conference concluded that the use of antibiotics to eradicate ulcer-causing bacteria essentially cures the disease and prevents its recurrence in most individuals. Because long-term bacterial infection has been linked to gastric cancer, additional research is needed to determine if the new treatment also may aid cancer prevention. Use of this inexpensive drug therapy could save billions of dollars annually in health care costs. In basic digestive diseases research with a prevention focus, NIDDK-funded scientists have discovered that inflammatory bowel disease [IBD] may be related to a newly discovered family of gastrointestinal "trefoil" peptides, which may have a role in stimulating healing. This advance typifies the kind of molecular understanding of disease that is needed to treat and prevent IBD. In liver research, we are beginning to understand how cells from transplanted livers may migrate into other tissues of the body, providing extra therapeutic benefits and potentially increasing immune tolerance of the transplanted organ. This research may shed light on ways to prevent transplant rejection. We are encouraged by these and other examples of recent progress in digestive diseases research. At the same time, however, this past year has witnessed an enormous tragedy at the NIH—the deaths of five patients who participated in a clinical trial of the drug FIAU. This drug had appeared to be a promising treatment of these patients with liver disease due to chronic hepatitis B infection. The tragedy caused by the unexpected and unrelenting toxicity of FIAU has touched us all very deeply and underscored the complexities of clinical research.

In kidney disease research, a continuing goal is prevention of end-stage renal disease [ESRD], whose treatment costs exceed \$10 billion annually under the Federal

Medicare Program for dialysis and transplantation. Following a successful pilot study, we are about to begin the full scale clinical trial of therapies for one of the most common causes of kidney failure in African-Americans: hypertensive kidney disease. In addition, we are launching a full scale trial aimed at preventing excess morbidity and mortality in hemodialysis patients. At the core of our kidney diseases research program are fundamental studies aimed at preventing the progression of different types of kidney disease—such as polycystic kidney disease and IgA nephropathy—to irreversible kidney failure. For example, we recently completed a multicenter prevention-oriented clinical trial, the study of “Modification of Diet in Renal Disease [MDRD].” This study concluded that blood-pressure control has a beneficial effect on the progression of certain types of renal disease.

The nutrition sciences offer promise of preventing or mitigating many health problems. As the principal NIH institute for nutrition, the NIDDK is enhancing trans-NIH coordination of the field through leadership of the Division of Nutrition Research and Coordination and through the development of NIH-wide scientific initiatives. An example of important nutrition research is studies of zinc, which is believed to be important in the immune response.

The Institute is continuing to extend its major initiative on prevention and treatment of obesity, a serious health problem of increasing prevalence, and a risk factor for diseases such as insulin-dependent diabetes, heart disease and gallstones. The cost of obesity treatments alone is almost \$40 billion per year, and treatment of associated disease complications costs billions more. The National Task Force on Prevention and Treatment of Obesity has prepared a draft report on “Obesity Research Directions” that includes a recommendation that NIDDK undertake a prevention initiative in obesity research. We have already begun this effort by co-sponsoring, with the NIH Office of Research on Minority Health, an important new clinical trial on “Longterm Outcome of Obesity Treatment in Minority Women.”

Gene therapy is one of the most exciting approaches to treating serious genetic disorders. Recently, NIDDK-funded researchers made a substantial gain toward gene therapy for muscular dystrophy. Embryos of mice with a damaged dystrophin gene, which would have led to a form of muscular dystrophy, were altered by insertion of a reduced-size version of the correct gene. These embryos developed into healthy mice with undamaged muscles. Although the challenge of administering this therapy to human cells is great, this success demonstrates the possibility of correcting the genetic defect.

While investigators continue to work toward gene therapy for cystic fibrosis [CF], patients will be helped by the development of an exciting range of new therapies. Particularly important advances include the development of the drug DNase to help digest the sticky mucus that clogs the lungs, the aerosol delivery of the antibiotic tobramycin, and a new device to vibrate airway walls and loosen mucus.

Combating urologic diseases is a central goal of NIDDK. Abnormal enlargement of the prostate gland affects most men over the age of 50 and may be related to the development of prostate cancer in some cases. NIDDK has launched the pilot phase of a clinical trial to examine the effectiveness of alternative drug and surgical treatments for this condition. Three new George O'Brien Kidney and Urologic Research Centers focus on prostate growth, including cancer, and we continue to work in a productive collaboration with the National Cancer Institute. Urologic researchers have characterized receptors for small peptides called endothelins, which are found in the bladder and other tissues. They are investigating the potential link of these substances to a range of urologic problems such as impotence and bladder irritability. Likewise, researchers have identified a protein similar to nerve growth factor that is produced in smooth muscle cells of the prostate, binds to a specific receptor on nearby epithelial cells and thus may be involved in proliferation of prostate cells. Exploiting these findings may lead to new treatments for various urologic disorders. In women's urologic disorders, the NIDDK is recruiting more than 1,300 people for the National Interstitial Cystitis Database Study.

NIDDK intramural scientists have been at the forefront of research on red blood cells over the past two decades, gaining vital knowledge about how genes are turned on and off. They have recently discovered the existence of “gene insulators,” which are special genetic sequences at the boundary between active and inactive genes. Ultimately, these insulator sequences may lead to improved techniques of human gene therapy, by protecting genetic material inserted therapeutically into a patient's DNA from inappropriate regulation. This kind of basic research is a foundation for future clinical advances. Progress has also been made in refining techniques of bone marrow transplantation to combat the cancer which commonly recurs due to undetected surviving malignant cells. Now, a new assay using PCR technology can assess post-transplant residual cancer cells and predict relapse. To promote additional mul-

tidisciplinary advances in blood research, the NIDDK will establish up to three new molecular hematology centers in fiscal year 1994.

Mr. Chairman, the budget request for NIDDK for fiscal year 1995 is \$742,547,000. I would be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. PHILLIP GORDEN

Born: December 22, 1934, Baldwyn, Mississippi; married, two children.

Education: B.A., Vanderbilt University, Nashville, Tennessee, 1957; M.D., Vanderbilt University School of Medicine, Nashville, Tennessee, 1961.

Professional history: 1961-62, Intern, Yale University, New Haven, Connecticut; 1962-64, Assistant Resident, Yale University, New Haven, Connecticut; 1964-65, USPHS Clinical Fellow in Metabolism, Yale University, New Haven, Connecticut; 1965-66, USPHS Research Fellow in Metabolism, Yale University, New Haven, Connecticut; 1966-74, Senior Investigator, Clinical Endocrinology Branch, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health; 1974-78, Senior Investigator, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health; 1974-76, Clinical Director, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health; 1976-78, Visiting Professor, Institute of Histology and Embryology, University of Geneva School of Medicine Geneva, Switzerland; 1978-present, Chief, Section on Clinical and Cellular Biology, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health; 1980-86, Clinical Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health; 1983-89, Chief, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health; 1986-present, Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

Professional organizations: American College of Physicians, American Diabetes Association, American Federation of Clinical Research, American Society for Clinical Investigation, Endocrine Society, American Society for Cell Biology, Association of American Physicians, American Society for Biochemistry and Molecular Biology.

Honors, awards: Alpha Omega Alpha Medical Fraternity, 1961; Doctor of Medicine (Honoris Causa)—University of Geneva, Geneva, Switzerland, 1986; Public Health Service Distinguished Service Medal, 1986; Public Health Service Commendation Medal, 1988; Distinguished Alumnus Award and Medal, Vanderbilt Medical School, 1990; Istituto Rotariano per l'Italia Meridionale [IRIM] Award of the Rotary International, Naples, Italy, 1992; Public Information Award of the Juvenile Diabetes Foundation, International, 1992; National Scientific Leadership Award, Crohn's and Colitis Foundation of America, Inc., 1993; Public Health Service Surgeon General's Exemplary Service Medal, 1993.

DIABETES DRUG

Senator HARKIN. Dr. Gorden, is that drug available now?

Dr. GORDEN. Yes; the drug is available now. But we did not know that this drug, which was designed as a drug to treat blood pressure, would have an effect on the course of renal disease independent of its effect on blood pressure. That is what this rather dramatic study shows.

Senator HARKIN. Was it just sort of serendipitous that you found that out or was it through an independent grant?

Dr. GORDEN. Yes; it was serendipitous, in the sense that this was first demonstrated in animals, in an animal experimental form of diabetes. And this drug was used essentially in a trial fashion, so the observation was serendipitous.

But that led to the application of this to this specific situation in diabetics with deteriorating renal function. Now, there is no question that we have to address all of these issues with prevention activities.

Your question is enormously pertinent because the rate at which we can address each one of these individual boxes that I have tried

to outline in terms of a broad-based plan depends totally on the resources that are available to us. Yes; it is true that our ability to move ahead and our resources are not tightly coupled and it is observations and discoveries like those resulting from this trial that all of a sudden open an opportunity. That is where I think we have to go in transmitting the results to diabetic patients. But the rate at which we do it must be a function of the resources that we have.

One other point is that this is an example of how we have been able to come to you over a long period of time and explain to you what our needs were and are with respect to the conduct of this trial, which was a very expensive trial, but with a huge payoff. You have essentially accepted our judgment on the basis of confidence that you have in us regarding the investment that was required.

We must continue to make that point. I use that example because I think that it demonstrates that the clinical trial has had enormous effect in terms of the public good, and I think that that credit really is very much directed to you and to your colleagues, who provided us with all this support.

REDUCTIONS IN FTE'S

With respect to the FTE's, I would like to just echo what Dr. Varmus has said. I think that it is the inflexibility of the system that is the most constraining. It is placing intramural research under an administrative barrier, essentially, that is the most constraining for us.

In our particular case, we have one of the lowest research management budgets in NIH, so we really do not have any room at all with respect to management to deal with the FTE issue. So the FTE reduction falls disproportionately on intramural programs, disproportionately on scientists who have nothing to do with middle level management. They are scientists running laboratories.

It is that inflexibility, from our perspective, that is the most deleterious to our program.

Senator HARKIN. I appreciate it. Thank you very much, doctor.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

GENE THERAPY RESEARCH

Question. There is a lot of discussion about the potential of gene therapy to cure disease. What kind of gene therapy research is being done at NIDDK? How much money is being devoted to this effort?

Answer. Gene therapy offers hope for curing many diseases that so far have eluded treatment. Decades of basic genetic research to identify and clone disease-causing genes have now made such therapy a plausible goal. This year there has been a major step forward in moving gene therapy from the laboratory to the bedside. Human gene therapy trials are being conducted for two genetic diseases, hypercholesterolemia and cystic fibrosis, and protocols have been approved by the NIH Recombinant DNA Advisory Committee [RAC] for phase I studies for the treatment of Gaucher's disease.

The NIDDK is supporting the human study of gene therapy for familial hypercholesterolemia. In this study conducted at the Gene Therapy Center at the University of Pennsylvania, researchers remove a portion of the patient's liver, isolate liver cells, insert a gene that produces the low-density lipoprotein receptor, and inject the genetically altered cells into the patient's liver where the cells colonize the liver and begin producing the protein that is critical to preventing the unwanted build-up of cholesterol. Unlike in previous gene therapy protocols, insertion of this gene should be permanent. In the first treated patient, gene expression has persisted for nearly two years and has lowered cholesterol levels by 20 percent.

The RAC has approved seven human phase-I trials for cystic fibrosis, and three are currently underway. Many of the protocols were developed with support from an NIDDK RFA issued in fiscal year 1992 entitled "New Therapies for the Treatment and Cure of Cystic Fibrosis." Most of these protocols use an adenoviral vector to deliver the corrected CFTR gene. One such study is being conducted at the Gene Therapy Center at the University of Pennsylvania. Another of the approved protocols that obtained its preclinical data with support from the NIDDK is the first to propose the use of liposomes to deliver the cystic fibrosis transmembrane regulator [CFTR] gene. In addition, research which was initiated in the NIDDK intramural program is underway at several universities to develop adeno-associated virus as a vector for delivery of CFTR to the lung.

The RAC has approved three protocols to begin phase I studies to treat patients with Gaucher's disease by using a retrovirus to introduce the normal gene into bone marrow cells. All three of the protocols involve researchers who obtained their pre-clinical data with support from the NIDDK. One of these studies will be supported by the NIDDK through the Gene Therapy Center at the University of Washington and another will be supported by a gene therapy program project grant.

These diseases represent only a fraction of the possible diseases treatable by gene therapy. Future targets for gene therapy include genetic hematologic, metabolic, kidney, and liver diseases, as well as disorders such as diabetes. In order to extend the repertoire of diseases that can be treated by gene therapy, the NIDDK supports basic research in identification and characterization of genetic diseases; development of vectors and gene delivery systems; and the identification and isolation of appropriate stem cell targets for gene therapy. Recently, investigators have brought two genetic kidney diseases closer to the possibility of gene therapy. The gene and mutations responsible for Alport syndrome, an inherited disorder that can lead to kidney failure and deafness, have been identified and cloned. Investigators have also mapped the gene for polycystic kidney disease.

To further encourage development and improvement of techniques for achieving successful human gene therapy, the NIDDK recently implemented new initiatives that focus on gene therapy research. In addition, the Institute will recompile its Specialized Centers for Cystic Fibrosis. It is anticipated that several of the competing applications will focus on gene therapy research for cystic fibrosis.

In summary, the NIDDK continues to support and foster research related to gene therapy in a variety of ways. The Institute looks forward to the contributions of the many investigators it supports to the development of modern methods of treating and curing disease.

In fiscal year 1993, the NIDDK's support of gene therapy research was approximately \$35 million.

GENE THERAPY CENTERS

Question. The fiscal year 1994 Senate report states that sufficient funds are provided to establish additional gene therapy centers at NIDDK. What action has been taken at your Institute to implement this recommendation?

Answer. In fiscal year 1993, in response to congressional appropriations report language, the NIDDK awarded two grants for core centers for gene therapy of cystic fibrosis [CF] and other genetic diseases. The University of Pennsylvania and the University of California at San Francisco were the recipient institutions. In fiscal year 1994, again in response to congressional appropriations report language, the NIDDK awarded a third gene therapy center grant, to the University of Washington.

In addition, in fiscal year 1994 the Institute will be reviewing another of its centers programs, the NIDDK Specialized Centers of Research for Cystic Fibrosis. The four existing Centers will compete with at least six other expected applicants for up to four grants. Some of the existing centers will be proposing new programs related to gene therapy, and the new Centers would emphasize gene therapy for cystic fibrosis, as well as basic research leading to new drug treatment for cystic fibrosis.

The NIDDK research agenda for CF is highly promising and reflects the Institute's commitment to conquering this disease, in part through the establishment of these cystic fibrosis and gene therapy research centers.

HEMATOLOGY RESEARCH

Question. Your Institute has a long record of support for research in hematology. Describe some of the highlights of this research and the directions your hematology research is now taking.

Answer. The NIDDK hematology program emphasizes a broad approach to understanding the fundamental processes underlying the normal and pathologic function of blood cells and the blood-forming system. Major areas of interest include hemoglobin structure, function, and genetic regulation; acquired and inherited hemolytic anemias; membrane composition and regulatory processes; iron metabolism, storage and transport; hematopoiesis and its regulation by growth factors, including erythropoietin; immunohematology and autoimmune disease; and transplant biology. The integration of advances in many of these areas has led to an effort to advance research on genetic therapies, and to the initiation of a new program of Centers of Excellence in Molecular Hematology.

Among the recent advances supported by the NIDDK hematology program are the following: studies showing that drug therapy can reduce anemia in patients with sickle cell disease and beta-thalassemia by altering hemoglobin expression, including recent findings from a collaborative phase I-II clinical study of arginine butyrate showing increased gamma globulin synthesis, reduced hemolysis, and clinical improvement in patients with beta-thalassemia; support of much of the research leading to the production of recombinant human erythropoietin for therapeutic use and continuing studies that are increasing the understanding of the molecular mechanisms involved in the production of erythropoietin by the kidneys; discovery that a defect in RNA alternative splicing involved in the production of different forms of a key red cell membrane protein leads to an inherited form of hemolytic anemia; development of an analytical system, using the polymerase chain reaction, to detect residual cancer cells in patients with chronic myelogenous leukemia after bone marrow transplantation and to help determine the origin (recipient or donor) of blood cells; and increased understanding of how as few as six class I major histocompatibility complex proteins (the proteins that identify and reveal the location of foreign proteins on surfaces of invading cells or viruses) bind to a wide variety of invaders by concentrating on a colon backbone structure.

Research directions within the NIDDK hematology program include the establishment of Centers of Excellence in Molecular Hematology to create a focus for multidisciplinary investigations into the cellular and molecular bases of genetic diseases of blood and to encourage the utilization of cellular and molecular biology techniques to characterize, identify, treat, and cure inherited diseases of the blood and other systems. The Institute is also encouraging grant applications for basic research on hematopoietic stem cell biology and hematopoietic gene regulation; hematologic consequences of HIV infection of marrow cells; and immune reconstitution of HIV-infected individuals.

QUESTIONS SUBMITTED BY SENATOR REID

INTERSTITIAL CYSTITIS

Question. As you know, interstitial cystitis is a debilitating bladder disease which mostly affects women. In fiscal year 1994, this Committee appropriated additional funds "to be used specifically for IC." Is this money being allocated specifically to address IC?

Answer. The funds appropriated by the Committee are being used to address all areas of research that could provide insight into factors that lead to a predisposition for, that initiate, and that influence the severity of IC. The cause of IC, its specific effect on the urinary bladder, its long-term natural history, the effect of previous or coexisting diseases on its development or severity, and the interrelationship between IC and other diseases of the bladder are all unknown. Current research initiatives are therefore designed to focus a cadre of investigators with a broad, comprehensive research background on solving the puzzle of IC.

UROLOGY STUDY SECTIONS

Question. Last year, the Committee included report language instructing NIDDK to consider the establishment of at least four urology study sections, one of which

would review female urology grants including Interstitial Cystitis, and requested that a report be submitted to the Committee by March 1, 1994. Has the NIDDK established such study sections? Has the NIDDK submitted its report?

Answer. Because the Division of Research Grants [DRG], NIH, has both the authority and the expertise to establish standing study sections at the NIH, the report requested by the Committee is being prepared by the DRG. The NIDDK does, however, select and convene special ad hoc review committees to review research grant applications submitted in response to Requests for Applications [RFA's] issued by the Institute. For the past few years, the NIDDK has issued several RFA's in urology. In those cases, the Institute has ensured that there is urologic expertise on the ad hoc review committee specific to the urologic area being addressed.

UROLOGIC DISEASES AFFECTING WOMEN

Question. What, in particular, has been done to address the need for research into urologic diseases affecting women?

Answer. Over the past years, the NIDDK has made a strong effort to increase meritorious research in the area of women's urologic health. In fiscal year 1993, the institute issued two Requests for Applications [RFA's], entitled "Interstitial Cystitis [IC] and Other Bladder Disorders of Women" and "Innovative Approaches to the Study of Interstitial Cystitis." In fiscal year 1994, the RFA "Interstitial Cystitis and Other Bladder Disorders of Women" was reissued, with the anticipation that 10 to 15 additional awards will be made in the areas of urinary tract infection, urinary incontinence, and IC. The NIDDK also supports an IC patient data base, with the objective of providing new insights and research leads related to IC. In March 1994, the Institute sponsored a 3-day "Symposium on Women's Urological Health." This symposium brought together speakers and participants from various research disciplines (including microbiology and infectious diseases, neurology, gynecology, pharmacology, surgery, physiology, epidemiology, and geriatric medicine) to focus on the problems of urinary tract infection, urinary incontinence, and IC. This opportunity for forging interdisciplinary collaborations was applauded by the participants and is likely to lead to new research approaches.

INFLAMMATORY BOWEL DISEASE

Question. What developments have been made in research into Inflammatory Bowel Disease? How have collaborations between IBD researchers and scientists in other disciplines positively affected research into IBD? How has the NIDDK utilized the gene bank in its research.

Answer. New developments in research into inflammatory bowel disease [IBD] have revealed that proteins known as cytokines act as mediators in regulating the body's inflammatory response. Understanding these regulatory factors may enable researchers to turn off the chronic inflammatory process that occurs in IBD. NIDDK-supported research on one cytokine led to drug treatment which resulted in clinical improvements in reduced diarrhea and blood in the stool, lessened pain, and decreased inflammation. New directions in diagnosis have led investigators to develop new markers of disease in IBD. Researchers have uncovered a difference in the response of immune cells from IBD patients' intestines as compared to normal patients when biologic factors that affect the immune system were added. Discoveries such as this provide a differential diagnosis of Crohn's disease from ulcerative colitis and aid in the search for cures. Investigators have identified an inexpensive mouse model which may provide important new information on how genetic and immunologic factors interrelate in causing an autoimmune-like chronic colitis, and make it possible to map specific IBD susceptibility genes. A new field of research is focusing on immunophysiology in the intestine. Modifying the immune system may cause important changes in intestinal junction and motility.

An example of the positive effect derived from collaborations between IBD researchers and scientists in other disciplines is the exploration of immune aspects of diseases being carried out by immunologists and rheumatologists. This kind of interdisciplinary research will generate fresh ideas and help to expand the base of investigators in the field. With regard to the gene bank, NIDDK grantees have studied, or are in the process of studying, families with more than one member with IBD. Along with these families, they have studied unrelated cases affected either with ulcerative colitis or Crohn's disease and their ethnically matched controls to further describe the genetic heterogeneity in IBD. This case-control association study was partially supported by the Crohn's and Colitis Foundation of America.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
STATEMENT OF PATRICIA A. GRADY, Ph.D., ACTING DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Patricia Grady, Acting Director of the National Institute of Neurological Disorders and Stroke.

Dr. GRADY. Thank you, Senator.

As you know, we conduct and support medical research in our Institute on over 600 neurological disorders affecting approximately 50 million Americans, at a cost of about \$400 billion to society per annum. Until recently we have had very little to offer in terms of the potential for treatment, or being able to determine the causes for these disorders.

That situation is changing. We are in the enviable position right now of being able to capitalize on a great deal of investment that has been made in the area of basic research. We are discovering how the brain works when things are working well and what goes wrong when the brain is not working well, and that has given us some tremendous insights into some of the mechanisms of disease and is enabling us to approach intervention and treatment in a rational fashion, and if not that at least to be able to stop some of these terrible diseases in their tracks.

NEUROGENETICS

Now, if we were to in fact receive a 50-percent increase it would allow us to capitalize on a number of these opportunities. I would direct your attention to three major areas. One of these is the area of neurogenetics. Over one-fourth of all genetic disorders affect the brain and the nervous system. Now, some tremendous advances have been made in the last few years in identifying genes for Huntington's disease, for ALS, and for many others.

[The statement follows:]

STATEMENT OF DR. PATRICIA A. GRADY

The National Institute of Neurological Disorders and Stroke [NINDS] is the lead Federal agency for research on the normal function of the brain, spinal cord, and peripheral nerves, and the diagnosis, treatment, and prevention of neurological and neuromuscular disorders. Over 600 disorders affect the nervous system, as a result of genes, trauma, infections, environmental factors, tumors, or inadequate blood supply. For example, stroke is the third leading cause of death in the U.S. An estimated twenty-five percent of all genetic disorders affect the nervous system. Permanent neurological disability that restricts daily activity affects about 50 million Americans at a cost to patients, families, and society of \$400 billion each year. Until very recently, there was little hope of finding the cause or a cure for most neurological and neuromuscular disorders, but that situation is changing. Pioneering examples of this new era of medicine include methods to prevent stroke, enzyme replacement therapy to reverse the course of an inherited metabolic disease, and the first-ever treatments to affect the course of multiple sclerosis and spinal cord injury. Neurological research efforts will continue to benefit Americans through improved

understanding of brain disorders and the development of a variety of prevention and treatment methods appropriate to different patient populations and methods to restore nervous system function.

Trauma is the leading cause of death in Americans under 45 years of age, and brain injury is a major factor contributing to this death rate. Economic costs associated with head and spinal cord injury are estimated at \$35 billion annually. Research supported by NINDS includes a clinical trial to expand treatment options for recovery from spinal cord injury and basic laboratory studies of methods to replace nerve cells and restore function.

Prevention efforts against stroke encompass the prevention of an initial stroke—as well as recurrent stroke—and strategies to limit damage to the brain following a stroke. NINDS-supported clinical trials have demonstrated the effectiveness of warfarin, aspirin, and surgery to prevent stroke in selected patient groups. Clinical trials now underway will tell us whether these methods can be extended to other patient populations. A new study has also been undertaken to learn whether estrogen can prevent a second stroke in post-menopausal women who have already experienced a stroke. Ongoing treatment studies are examining several approaches including new agents that target the blood clotting process in an effort to restore or maintain blood flow, preserve function, and improve recovery. We also need to know more about risk factors for stroke and the impact of stroke among different populations within the U.S. Three epidemiological studies currently address that issue. Intramural stroke research includes a focus on finding why risk factors trigger stroke. In 1993, NINDS joined with voluntary organizations to issue guidelines on the emergency treatment of stroke. This year, NINDS plans to publish two brochures addressing patient education and stroke prevention.

Neurological disorders in children are especially tragic because of the early and lifelong impact on physical and social development and educational opportunities. NINDS supports and conducts a spectrum of studies with the common goal to determine what has gone wrong and how to correct neurological dysfunction in children. For example, recent findings from an epidemiological study show that twins are at higher risk for cerebral palsy—an important finding in view of the increasing numbers of multiple births. Research on brain injury in the newborn includes a focus on bleeding in the brain, congenital hydrocephalus, and seizures. As a disproportionate share of minority infants are born early and underweight, they are at risk for many of these conditions as well as for language and motor disabilities. NINDS has established four pilot research centers in neonatal brain injury that involve laboratory, animal, brain imaging, molecular biology, and clinical studies to foster discovery of mechanisms of damage in the neonatal brain and therapeutic strategies appropriate to the newborn.

Research progress to understand and treat epilepsy, affecting approximately one percent of the population, depends upon a broad-based research program to improve diagnosis, treatment, and prevention strategies. NINDS supports and conducts basic laboratory studies to understand the mechanisms of cell signalling, since seizures are the visible result of nerve cells firing out of control. Through the Antiepileptic Drug Development (ADD) Program, compounds are identified and evaluated for their safety and effectiveness as anticonvulsants. It was through this program that the therapeutic potential of Felbamate, the first new epilepsy medication in fifteen years, was identified. Intramural and extramural efforts are expected to result in additional medical and surgical strategies to prevent seizures.

Selective degeneration and death of specific groups of nerve cells are the hallmark of several serious neurological disorders, including amyotrophic lateral sclerosis [ALS], Parkinson's disease [PD], and progressive supranuclear palsy [PSP]. The first gene for a neurodegenerative disorder of adult life was identified in 1993 by NINDS-supported scientists when they discovered a defective gene that causes a type of ALS that occurs in a small number of families. Because the normal gene produces an enzyme that neutralizes the effects of free radicals, the discovery implicated free radicals as a culprit in ALS, and encouraged further study of their role in other neurological disorders. ALS research efforts include the pursuit of other genes implicated in ALS and studies of growth factors that may promote healthy function and prevent nerve cell death. Research efforts in Parkinson's disease and related disorders include studies of environmental and endogenous toxins, genetic predisposition, and altered chemistry within nerve cells. Ongoing treatment research in PD includes a clinical trial to evaluate the efficacy of fetal tissue implants, intramural studies of several novel approaches to improve symptom management and modify the course of the disease, and further clinical evaluation of deprenyl and antioxidants.

For some neurological disorders such as multiple sclerosis [MS], the problem is not in the neurons that transmit signals, but the myelin sheath that surrounds neu-

rons to provide insulation that is affected. Although MS is believed to be an autoimmune disease, the precise factors that trigger MS are being addressed through research that may lead to strategies to treat and prevent the disease. These factors include genetic, viral, immune, and perhaps other unknown influences. Basic research to understand the formation of myelin, the major component of the insulating cells, should have applications to MS and other demyelinating disorders.

Patient studies of gene-based therapies for neurological disorders have been launched. NINDS intramural scientists, who are at the forefront of efforts to find new ways to deliver anti-cancer agents to the brain, have obtained encouraging results from the first clinical evaluation of a therapy to genetically modify brain tumor cells to make them vulnerable to antiviral medications. The technique, developed with scientists from NCI, will soon be expanded to patients with other types of brain tumor. Intramural scientists will soon launch the first gene therapy trials for Gaucher's disease. NINDS will encourage new efforts in gene therapy for Duchenne's muscular dystrophy and has also joined with NIDDK to encourage new methods of gene therapy for inherited metabolic diseases such as Batten disease. Recent progress in efforts to identify the cause of neurological disorders includes the genes for spinocerebellar ataxia and neurofibromatosis type 2, and success by intramural scientists to narrow the search for the gene for Niemann-Pick Type C disease. Increased efforts will explore the regulation and control of genes, which may lead to creative approaches to treat nervous system dysfunction.

More than half of the people infected with HIV develop neurological complications. NINDS scientists and grantees have identified many of the neurological manifestations of HIV in children and adults. Recently, collaborations with the AIDS Clinical Trial Group have been initiated.

Mr. Chairman, the fiscal year 1995 budget request for this Institute is \$630,443,000. I would be pleased to answer any questions you might have.

BIOGRAPHICAL SKETCH OF PATRICIA A. GRADY

Education: B.S.N., Georgetown University, Washington, DC, 1967; M.S., University of Maryland, Baltimore, MD, 1968; Ph.D., University of Maryland, 1977.

Professional history: Acting Director, NINDS, 1993 to present; Assistant Director, NINDS, 1992-93; Program Manager, Stroke and Brain Imaging, Division of Stroke and Trauma, NINDS, 1988-92; Member, Rehabilitation Task Force leading to National Center for Medical Rehabilitation Research; NINDS Liaison to National Center for Nursing Research; Member, Advisory Group, NCMRR, NICHD, NIH representative to Interagency for Disability and Rehabilitation Research for Director, NIH; NINDS representative to Diagnostic Radiology Coordinating Committee; Research Assistant Professor, University of Maryland School of Medicine, 1980-88; Director of Cerebrovascular Physiology Research Laboratory, Graduate Faculty Member; Lecturer, Maryland Academy of Sciences; Assistant Professor, University of Maryland, School of Nursing (Joint Appointment), 1979-88; Consultant to Doctoral Program in Nursing (Ph.D.); Instructor, University of Maryland School of Medicine, 1977-80; Research Associate, 1976-77; Assistant Professor University of Maryland School of Nursing, 1970-73; Acting Director, Senior Medical/Surgical Nursing Division; Director of Neurological and Neurosurgical Nursing Specialty; Member, Faculty Council; Chairperson, Student Health Committee; Student Government Advisor; Maryland State Nurses' Association Secretary; Instructor, University of Maryland School of Nursing, 1968-70; Instructor, Washington Hospital Center School of Nursing, Washington, DC, 1966-67; Director, Newborn Division, Maternal and Child Health Department.

Professional organizations: American Association for the Advancement of Science; American Academy of Neurology; Fellow, American Heart Association, Stroke Council; New York Academy of Sciences; Society for Neuroscience; Sigma Theta Tau National Honor Society; American Nurses Association; Council of Nurse Researchers; American Society for Professional and Executive Women; American Lung Association, Professional Education and Training Committee; Executive Board, Stroke Council, American Heart Association; Budget Committee, Stroke Council; Committee for the Development of Clinical Research in Stroke, Stroke Council, American Heart Association; National Advisory Voluntary Board of American Heart Association; Neurotrauma Society; Editorial Board, *STROKE*.

Honors, awards, fellowships: Sol Greenberg Award for Leadership Ability and Clinical Excellence, Saint Francis Hospital School of Nursing; State Finalist for "Student Nurse of the Year," State of Connecticut; Dean's List, Georgetown University; Sigma Theta Tau National Honor Society; DHEW Graduate Traineeship—Division of Nursing for Master of Science Degree; NIH Predoctoral Fellowship for Doctor

of Philosophy Degree; NIH Individual Postdoctoral Fellowship (Neuropathology); Elected Fellow, Stroke Council, American Heart Association; Executive Committee Member, Stroke Council, American Heart Association; Member, Search Committee, Editorship of Stroke, NIH Merit Award.

GENETIC DISORDERS

Senator HARKIN. Excuse me. About how many genetic disorders affect the brain?

Dr. GRADY. About one-fourth of all genetic disorders affect the brain and the nervous system, and identifying these genes is extremely important. What that does is to give us a handle on finding the causes of the disease.

But then the next step after the very important first step of finding the gene, which Dr. Collins will tell you more about, is identifying what the gene does and then being able to intervene in the disorder caused by the faulty gene. This is an area that we see very great promise in.

CNS INJURY

Another area of opportunity is that of central nervous system injury, which includes primarily spinal cord injury, brain injury, and also stroke. A great deal has been learned about what happens at the time of a stroke or a central nervous system injury of a traumatic sort, what happens at the time and what can be done to limit the disability, and the so-called secondary events, which occur at the time of injury and result in extension of a lesion and in more extensive brain death.

We now are identifying ways to stop some of that damage. We know about some of these already, with first early treatments of spinal cord injury and some forms of stroke. In fact, Senator, you will be reading in the paper tomorrow about yet another breakthrough in stroke, the use of aspirin as opposed to anticoagulants in some patients with irregular heartbeat.

Because the use of aspirin appears to be indicated as opposed to a more expensive anticoagulant approach, that in fact will save probably close to several million dollars per year in health care costs to the Nation. Again, this is an area in which we see a great deal of promise.

Stroke used to be a condition for which if it occurred, there was nothing you could do. Now, because of the research that has been done, we have identified stroke as an acute disorder. Something can be done.

NEURODEGENERATIVE DISORDERS

A third area that I would like to draw your attention to is that of neurodegenerative disorders of the brain. For some of these disorders, we have identified the gene as in Huntington's disease. For others, as in the area of multiple sclerosis, the first treatment has been identified. More needs to be done to find out how to prevent myelin breakdown in multiple sclerosis and, in fact, how to prevent the progression of the disease.

Another area of importance is Parkinson's disease. Again, the neurodegenerative disorders are very damaging in that they affect people in their midyears and then progress as they get older. The

positive side of that is, because they do develop slowly, there is an opportunity for us to intervene at an early stage to try to protect the viable nerve cells that are injured, but are still able to operate, to learn about the communication between them, to try to prevent further damage.

A number of interesting findings about how nerve cells communication have come out recently and those findings provide the basis for some potential treatments. One of the things we have found out is that a major transmitter, glutamate, that you have heard about several times may be involved. Dr. Varmus referred earlier this morning to how nerves communicate with one another and how important it is to keep that process working smoothly. Well, in fact glutamate is one of the things that does this. It is a transmitter of messages between nerve cells.

Well, it turns out that there are a number of situations in which glutamate can overstimulate in some of the neural disorders. We knew that in acute situations such as stroke or CNS injury. We did not know that it could happen in the area of degenerative disorders. It turns out that the neurotransmitter, glutamate, as it is released normally stimulates nerve cells, so it excites the other cells to send messages through.

But in the case of neurodegenerative disorders too much glutamate is released or it is not broken down properly, and it literally excites these nerve cells to death. We think that we have a chance to prevent that from happening.

These are some of the areas that are most exciting for us right now. Again, there is a major concern. Scientists are excited, the patients are waiting, and it is a story that we have been telling in very short chapters. We do not know the end of the story, but we will be able to tell you soon, sooner as opposed to later, depending on the resources.

For the people that are out there waiting every moment is just much too long.

SUCCESS RATE

Senator HARKIN. I should have asked—I have gone over my time. I am going to do this differently next year.

But anyway, what percent of grants are being funded in your Institute?

Dr. GRADY. Our funding success rate is approximately 22 percent this year, Mr. Chairman. About one out of four applications that we get is funded; if we were to receive the increase that you suggest we would be able to fund roughly 40 to 50 percent. This would make an enormous difference, as you have heard already and you will continue to hear as we go around the table.

FTE REDUCTIONS

With regard to the FTE situation, we are affected in a similar fashion to the other Institutes. As a medium-sized Institute, we already have a limited number of 14, 15, and SES positions. One of the situations that we daily deal with is being able to reward our particularly outstanding people with promotions and to be able to recruit people into those higher levels.

We often get wonderful people employed and we train them, and we lose them to our larger colleague Institutes. So we would particularly be affected by the restrictions in the number of 14 and 15 and SES level positions.

Senator HARKIN. Thank you very much, Dr. Grady.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

PARKINSON'S DISEASE RESEARCH

Question. The fiscal year 1994 Senate Committee report directed NINDS to submit to the Committee a report outlining: "potential treatment options and progress toward identifying a cause; current funding levels by Institute for supporting Parkinson's-related research; and a plan for developing a coordinated research agenda among the appropriate Institutes."

Dr. Grady, what is the status of this report? Are you prepared to answer some of the specific questions to be addressed by that report. Namely, what are the current and past funding levels for Parkinson's? What is the NIH or any of its Institutes doing to develop a strategy for a breakthrough in Parkinson's treatment? What coordination of efforts among the various Parkinson's-related Institutes is underway or planned?

Answer. The report on Parkinson's disease research conducted by seven Institutes and one Center in the National Institutes of Health [NIH] was completed at the NIH in February, 1994. It is currently under review by the Department of Health and Human Services. Current and past funding levels for Parkinson's disease research at these eight organizations is displayed in the accompanying table. Total funding levels reported increased from \$64.6 million in fiscal year 1992 to a projected \$75.3 million in fiscal year 1994.

The report presents a comprehensive and well integrated research program for Parkinson's disease at the NIH, and includes programs, research accomplishments, initiatives, and an assessment of research opportunities from the eight NIH institutes and centers within a coordinated process—all aimed at discovering the cause(s) of Parkinson's disease, developing improved treatment, finding ways of prevention, and ultimately curing the disorder and restoring function to those who have lost it. The National Institute of Neurological Disorders and Stroke [NINDS] is the focal point and major supporter of Parkinson's disease research within the NIH. However, since the brain not only exerts control over but is also influenced by all body systems, relevant research falls under the purview of several NIH components:

- The National Institute on Aging has an interest in research on Parkinson's disease as a disorder with a higher incidence among the aging.
- The National Institute of Mental Health has special interest in conducting research on the behavioral aspects of Parkinson's disease.
- The National Institute of Environmental Health Sciences supports research investigating possible environmental elements that may relate to Parkinson's disease.
- Other institutes have research interest in the biology of the brain relevant to Parkinson's disease—nervous system transmitters, receptors, tissue implants, etc. The basic and related research they contribute is essential to a full understanding of the disorder and development of methods of prevention and treatment.

Many of the initiatives are joint ventures among multiple NIH Institutes in the form of joint funding and collaborative activities and initiatives. Several NIH research and funding mechanisms promote coordinated research on Parkinson's disease:

- Great care is taken through the use of NIH-wide referral guidelines to assure that research grant applications are assigned to the Institute or Center with the closest match in terms of mission.
- Institutes invite participation of other NIH components in joint grant application solicitations. All planned solicitations are circulated to other components of

the NIH for possible cosponsorship. For example, in 1993, a solicitation for grant applications concerning methods for characterizing human fetal tissue for transplantation, for example in Parkinson's disease, was cosponsored by the NINDS, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Institute of Child Health and Human Development.

—Inter-institute committees and task forces bring institutes' representatives together to coordinate planning and research. For example, the Task Force on Aging Research has developed research plans concerning Parkinsonism among the aging population.

—Additionally, collaborations between institutes' intramural laboratories occur when parallel scientific lines of inquiry develop. For example, NINDS and NIMH scientists are now collaborating on studies of the nerve cell receptors and transmitters involved in Parkinson's disease.

NIH PARKINSON'S RESEARCH

[In thousands of dollars]

	Fiscal year—		
	1992	1993	1994
National Institute of Neurological Disorders and Stroke	\$39,743	\$44,978	\$46,730
National Institute on Aging	10,270	9,851	10,151
National Institute of Mental Health	5,812	5,504	5,760
National Center for Research Resources	1,031	2,257	2,323
National Institute of Diabetes and Digestive and Kidney Diseases	864	973	1,000
National Institute on Drug Abuse	6,900	7,590	8,350
National Institute of Environmental Health Sciences	591	666	826
National Institute of General Medical Sciences		115	115
Total reported	65,211	71,934	75,255

QUESTIONS SUBMITTED BY SENATOR INOUE

MOVEMENT DISORDERS RESEARCH CENTERS

Question. Would movement disorders research centers in the private sector be likely to stimulate research of the "rare" movement disorders, such as progressive supranuclear palsy, which have been so far, largely neglected by the public sector?

Answer. Research centers can provide a favorable environment for studying difficult research questions because they provide a setting in which basic and clinical investigators can collaborate. However, the availability of promising research approaches is critical to the advancement of a new field. Centers represent only one approach to stimulating the interest of the research community to seek out and pursue opportunities in research on movement disorders.

Question. The NINDS intramural research studies are well known. Would private sector research centers in movement disorders enable NINDS to expand those intramural studies into "rare" movement disorders?

Answer. The NINDS intramural research program is already in the forefront of research on rare movement disorders such as progressive supranuclear palsy and dystonia as well as Parkinson's disease, a more common disorder. In general, it is not usually the case that growth in an extramural program is mirrored by expansion of the intramural counterpart. One of the most important roles of the intramural program is to focus on research problems that are not being adequately explored in extramural settings.

Question. Can these centers be established from the Administration's existing proposed budget for fiscal year 1995?

Answer. The budget proposal for fiscal year 1995 does not include funding for movement disorder centers.

Question. In your view, how much additional funding would be necessary to establish five new centers for movement disorders research, and provide initial grants for their start up?

Answer. Funding for five exploratory center grants would require approximately \$2 million annually for the initial (three-year) award. Should any of those centers compete successfully for funding as a full-fledged center, costs would rise to approximately \$1.2 million per center per year.

Question. In your opinion, are research centers the best mechanism for increasing research in the movement disorders? (If the answer is "No", "What is a better mechanism?")

Answer. A small number of pilot centers for the study of movement disorders could play a significant role in accomplishing research goals. Five may well be too ambitious a target, given the lack of promising leads and the limited response to earlier program announcements. Other options include solicitation of investigator-initiated research, either as freestanding projects or supplements to ongoing grants in closely related areas such as Parkinson's disease, and research workshops. NINDS held a workshop on dystonia in February, 1993 and another on neuropathological diagnosis in PSP in November, 1993. Publications from those meetings are expected to stimulate additional interest and research activity concerning these two movement disorders.

QUESTIONS SUBMITTED BY SENATOR HATFIELD

Question. Dr. Grady, last year, the Committee report called for a greater commitment to Parkinson's disease research. Would you tell us how much NIH devoted to this particular field of study last year, and how much is proposed for fiscal year 1995? Would you tell us exactly how much of that total is allocated specifically for Parkinson's research?

Answer. The funding by Institute for Parkinson's Disease Research, both direct and related follows:

PARKINSON'S RESEARCH

[In thousands of dollars]

ICD	Fiscal year 1994—			Fiscal year 1995—		
	Direct	Related	Total	Direct	Related	Total
NINDS	\$19,036	\$27,694	\$46,730	\$19,606	\$28,848	\$48,454
NIA	5,380	4,771	10,151	5,544	4,916	10,460
NIDA		8,350	8,350		8,500	8,500
NIMH	2,003	3,757	5,760	2,042	3,930	5,972
NCRR	2,323		2,323	2,443		2,443
NIDDK		1,000	1,000		1,100	1,100
NIHRS	450	376	826	468	378	846
NIGMS		115	115		115	115
Total	29,192	46,063	75,255	30,103	47,787	77,890

Question. Dr. Grady, while I recognize the budget constraints you are under, I am concerned that insufficient funds have been devoted to Parkinson's research over the past several years. Is the problem a lack of grant applications? Would you tell us how many applications for Parkinson's research were submitted in fiscal years 1993 and 1994, and how many of those were funded.

Answer. NINDS funds 1 of every 4 applications reviewed. The decision to fund a project is based largely on the scientific merit of the application as judged by a peer review. In fiscal year 1993 only 16 (28 percent) of 56 applications that directly address Parkinson's Disease fell within the top 40 percent of the applications judged to have the highest scientific merit based on percentile scores. The problem is not necessarily the number of applications received, but the competitive quality of the applications.

There were 1,786 Research Project Grant applications reviewed for NINDS in fiscal year 1993, of which 192 were related to Parkinson's research. Of the 192 applications, 66 focused directly on Parkinson's Disease. The number of Parkinson's related Research Project Grants funded in fiscal year 1993 was 31. Of the 31 applications 10 were direct Parkinson's Disease. We expect to review 1,850 applications in fiscal year 1994. The first two National Advisory Neurological Disorders and Stroke Councils reviewed 138 applications for Parkinson's research. Of the 138 applications, 51 were direct Parkinson's Disease. The number of Parkinson's related Research Project Grants funded in fiscal year 1994, through the two Councils, is 15. Of the 15 applications, 4 are direct Parkinson's Disease.

QUESTIONS SUBMITTED BY SENATOR STEVENS

NERVOUS SYSTEM RESEARCH/NINDS DIRECTOR

Question. I have been concerned for some time that our level of support for neuroscience research has been lacking, and I am particularly concerned given the information we now have about the age structure of our population by the year 2025.

The data I have reviewed indicates that nearly 67 percent of nursing home residents, for instance, have cognitive disabilities and problems with activities of daily living. These disabilities could include dementias, psychiatric conditions, affective states, substance abuse, and mental retardation.

If we rely on assisted living, home care and hospice as less expensive alternatives to institutional care in this struggle for compassionate care, we must endeavor to have the science there to meet those demands.

(a) What plans are there in the next five years to invest in research in neuroscience, the study of the brain and the nervous system? (b) Has the President sent any names forward to be director of the National Institute on Neurological Disease and Stroke?

Answer. As shown in a report describing the Decade of the Brain research programs and plans prepared by the National Institutes of Health [NIH] and submitted to the U.S. Senate in the spring of 1993, twenty-one NIH Institutes and Centers are supporting research on the brain and nervous system. In total, these programs and initiatives represented an NIH expenditure of \$1.82 billion in fiscal year 1992 and an estimated \$1.89 billion in fiscal year 1993. In addition, the NIH Office of the Director also contributes to DOB activities through joint funding and collaborative activities and initiatives sponsored by the Office of Research on Women's Health, the Office of Minority Programs, the Office of AIDS research, and the Office of Disease Prevention. Research is providing the basis for understanding brain function and dysfunction. With this understanding comes the potential to conquer the hundreds of diseases and disorders that afflict the brain and the systems with which the brain interacts through the development of effective therapies and strategies for prevention of these disorders. Taken together, the programs, initiatives, and plans presented in this report represent a National Institutes of Health plan of action for the Decade of the Brain through the year 2000.

While the position of Director of the National Institute of Neurological Disorders and Stroke [NINDS] is not a Presidential appointment, Secretary Shalala, Assistant Secretary Lee, and National Institutes of Health Director Varmus are working to finding a person of the highest caliber to lead the NINDS into the 1990's and beyond. The initial search has been concluded and the applicants are now being assessed.

 QUESTIONS SUBMITTED BY SENATOR COCHRAN

NIH RESEARCH CENTERS FOR MOVEMENT DISORDERS

Question. Will there be any funds earmarked within the National Institute for Neurological Disorders and Stroke to establish these research centers?

Answer. The proposal to authorize these centers is contained in pending legislation, and so specific funding for this activity was not included in the President's budget.

Question. Are there any obstacles to the NIH's involvement in this project?

Answer. There are no legal obstacles to NIH involvement; the proposal is consistent with current operating authority.



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Fauci, Director of the National Institute of Allergy and Infectious Diseases. On the FTE's why do you not just submit that for the record. I would like to see what it looks like.

Dr. FAUCI. I would be happy to.

FUNDING INCREASE

Senator HARKIN. Dr. Fauci, welcome back. Good to see you.

Dr. FAUCI. Good to be here, Mr. Chairman.

With regard to the first part of your question, about the opportunities attendant upon a 50-percent increase in resources for the National Institute of Allergy and Infectious Diseases, as you know, the mandate of our Institute, infectious diseases and diseases of the immune system, either by hypo or hyperfunction, are diseases that are eminently preventable and eminently treatable, particularly with regard to the infectious diseases.

I would reiterate and echo the statements of my colleagues concerning the commitment to fundamental basic research. This has been particularly relevant in the study of microorganisms and the cellular molecular biology associated with infectious diseases and diseases of the immune system.

If one looks at our grant applications, of the unsolicited research project grants, apropos of the statements about the award rate, we feel very strongly and, as Dr. Varmus has mentioned, that when you get down to grants within the top third you really cannot make any real substantive distinctions between many of those within that group.

So we would place a considerable emphasis, as we have done in the past, on funding the fundamental basic research and bringing that award rate well above where it is now. We believe that an award rate of at least 45 percent in the area of fundamental basic research would be appropriate.

But also in our Institute, very closely married to unsolicited basic research, are certain areas that would benefit from the kinds of increases you are talking about. I will mention just a few. Sexually transmitted diseases are one of the most important diseases in this country with regard to morbidity, particularly among women and children born of women who have sexually transmitted diseases at the time of birth and delivery.

We have prevention research programs that can be expanded, which interdigitate with the fundamental basic biology and behavioral changes that are necessary to prevent the transmission of disease. In addition, we need better diagnostics.

One of the truly untapped areas vis-a-vis what we need to do in the future is developing effective vaccines for sexually transmitted diseases. Hepatitis B is an infectious disease that can be transmitted sexually, but that is the only one that we have an effective vaccine for, despite the fact that there are so many sexually transmitted diseases.

We also need much more work in the area of immunogenetics, particularly in the African-American and Hispanic populations where HLA typing for transplants of all different types of organs falls far behind what we have for the Caucasian population. Moreover, fundamental research in autoimmunity and understanding how we can tolerize the body against certain antigens or proteins is critically needed.

These are all research areas that are perched for the resource expansions you are talking about. With regard to the prevention or vaccine development component, research opportunities exist that have public health implications and are cost effective. Right now, we are seeing a revolution in molecular biology; we are able to develop new and improved vaccines for diseases. Moreover, we are able to improve upon existing vaccines, so that we do not need to give three or four shots to protect an individual; instead, we are able to provide long-lasting, life-long immunity with a single shot of a variety of antigens that protect against many of the infectious diseases to which we are exposed.

We are also very much aware that greater than 50 percent of our Institute is involved in AIDS research and rightfully so since this is the Allergy and Infectious Disease Institute, and AIDS is an infectious disease of the immune system. You have heard and you mentioned that one of the things you are concerned about is the role of basic research in AIDS.

Our Institute is committed to basic research and we could effectively spend extra money to study the fundamental basic components of this disease. We refer to this as pathogenesis, and it relates to how this virus destroys the body's immune system. There are still many unanswered questions that, when answered, would serve as a good solid fundamental basis for therapeutic and preventive strategies.

The same holds true for studying, for example, the acute early primary phase of infection; also, obviously, the targeted development of new drugs. You heard about protocol 076, in which pregnant HIV-infected women were given AZT to block the transmission to their infants, and it produced excellent results.

Protocol 076 used a drug that, even though it is a good drug, hopefully will not turn out to be the best drug that we have. So the use of structural biological approaches to target antiviral agents will result in new drugs being developed in the future which will compound in a positive way what we saw in that trial. These new drugs may also be beneficial to people who in fact are already infected.

Finally, with regard to an effective vaccine for HIV infection and HIV disease, we need to closely marry the fundamental basic science with the infrastructure that is necessary to execute a vaccine trial once a suitable candidate vaccine is developed.

I will submit for the record the numbers regarding the FTE's.

[The information follows:]

FTE REDUCTIONS

The full-time equivalent [FTE] reductions will compromise NIAID's ability to respond to Public Health exigencies, and it will impede our ability to capitalize on changes in scientific direction in a timely manner. In our Intramural Research Program, several program areas would be curtailed: vaccine development studies on parainfluenza and chlamydia; basic research studies investigating issues related to immunology and host defense against infections such as Lyme disease, tuberculosis, and AIDS; projects studying gene therapy and the use of cytokines in infectious diseases; and studies investigating how the immune system chooses between inflammatory versus allergic modes of response. The application of knowledge gained on the basic mechanisms of antigen presentation to the design of effective vaccine strategies, especially the elicitation and maintenance of CD8 cytotoxic responses to HIV, will be curbed.

Continuing reductions in staffing levels will delay the implementation of new programs such as those focusing on *Mycobacterium tuberculosis*, chlamydia, salmonella, autoimmune and inflammatory diseases, and novel approaches to developing new and improved vaccines.

Moreover, FTE reductions will result in the loss of tenure track investigators who are unable to hire the technicians needed in support of their research programs. Also, the impact of the freeze on promotions to grades GS-14 and above will impede our ability to retain the very best young scientists or provide career opportunities to promising new scientists.

FTE reductions will also impact on the regulatory functions of our Extramural Program as well. With the reduced staffing levels experienced to date, NIAID's review staff is unable to evaluate applications in a timely manner; thus, deferrals and delays in making awards are occurring. Additional reductions will exacerbate this situation. In our AIDS program, FTE reductions will impede our ability to continue our regulatory and legal responsibilities as an Investigational New Drug sponsor and impact on the management and operation of our treatment and vaccines clinical trials programs.

PREPARED STATEMENT

Dr. FAUCI. Everything I said in the area of new initiatives will be hampered with regard to the FTE cuts that we are talking about. My own Institute will be reduced between 95 and 100 FTE's over the period of time that we are talking about. So we would not be able to initiate, launch, and monitor the very exciting projects that I outlined briefly for you, nor would we be able to capitalize on the exciting research opportunities that exist in our very competent intramural laboratories. In fact, our intramural laboratories will actually have to be reduced. And that is very painful and not good for science. When you have scientists who are very excited about their work being told that the people we said they could hire cannot be hired and, in fact, we have to take away positions from them, that is something that is just not good for the research effort we are talking about.

[The statement follows:]

STATEMENT OF DR. ANTHONY S. FAUCI

The developed world today enjoys a level of public health higher than at any previous time in history, largely due to the availability of vaccines, antibiotics, sophisticated diagnostic tests and other technologies. Some of the accomplishments of this century have been remarkable: smallpox has been eradicated through worldwide vaccination efforts, and polio has been virtually eliminated in the western hemisphere. In the past decade at least nine new or improved vaccines have become available.

Despite these extraordinary successes, however, many challenges to our Nation's health remain. The human immunodeficiency virus [HIV] and its associated complications continue to devastate the lives and families of men, women and children,

especially in our inner cities. In recent months, infectious organisms have compromised the water supplies in several of our cities. Drug-resistant strains of pathogens, such as those that cause tuberculosis [TB], now elude once-effective therapies. Sexually transmitted diseases [STD's] are widespread, especially among our young people. Obscure microbes have emerged to cause serious outbreaks of disease, such as the Hantaan virus seen in the southwest United States. Asthma rates have risen among minority children in our cities. The number of people needing organ transplants, especially in minority populations, is rising each year.

These trends emphasize that the mission of the National Institute of Allergy and Infectious Diseases [NIAID]—preventing, diagnosing and treating infectious diseases and disorders of the immune system—is more vital than ever. The research programs at NIAID, which range from basic studies of the immune system to behavioral interventions, reflect the Institute's mandate to reduce the burden of disease in both human and economic terms. Underpinning these efforts is the work of basic researchers: bench scientists working toward a better understanding of the biology of microbes, how they invade the body and cause disease, how the immune system responds, and what responses are protective. A detailed understanding of the immune system is especially critical to understanding immunologically mediated conditions such as asthma, allergies, the rejection of transplanted organs, and the acquired immune deficiency syndrome [AIDS].

NIAID's research programs hold special promise for helping minorities and women, who bear a disproportionate burden of certain conditions. In the inner city, people of color suffer rates of infectious diseases such as TB, HIV infection and sexually transmitted diseases [STD's] far higher than the population as a whole. End-stage kidney disease, with the resulting need for a kidney transplant, is four times more prevalent in African-Americans than in whites. Autoimmune diseases are six times more common in women than in men. Research into the prevention or treatment of all of these conditions falls under the purview of the NIAID.

Vaccines are the public health tools that offer the greatest potential to reduce death, illness and health-care costs. NIAID-supported researchers are developing new classes of vaccines to protect individuals from acquiring viral, bacterial, parasitic and fungal infections, and are employing biotechnology to improve older vaccines that are based on weakened or killed microbes. NIAID also contributes to the research component of the Children's Vaccine Initiative, a global program to develop safe and effective vaccines.

HIV infection is spreading throughout the world at an alarming rate. According to various estimates, 40 to 110 million people could be infected with HIV by the year 2000. The development of a vaccine that would prevent HIV infection or HIV disease is a national and international health priority. NIAID is pioneering the development of HIV vaccine candidates by employing new genetic engineering and molecular biology technology. At the same time, the Institute is establishing the infrastructure for conducting large-scale clinical trials as soon as suitable candidate vaccines are identified.

Traditionally, live, attenuated or weakened viruses have proven to be the most effective vaccines. Promising results have been obtained recently with an experimental vaccine that protected monkeys against an HIV-like retrovirus known as simian immunodeficiency virus [SIV]. The vaccine was created by deleting one SIV gene. Attenuated SIV vaccines are now being constructed with four or five genetic elements deleted, thus providing an extra margin of safety. If these prove to be safe and effective in monkeys, similar approaches may be cautiously pursued in man.

For those already infected with HIV, it is crucial to develop therapies that prolong and improve the quality of life. In the past year, studies conducted by NIAID researchers have increased our knowledge of the multifactorial, overlapping processes that enable HIV to progressively weaken the immune system. This information is being used in the development of comprehensive treatments directed at a number of different disease mechanisms, particularly those that occur during the early phase of infection, when the virus spreads rapidly throughout the body.

The study of HIV infection in women is a major focus of NIAID research. We recently initiated a large-scale project to study the signs and symptoms of HIV infection in women, describe the pattern and rate of their immune system decline and examine potential co-factors that may affect their disease progression. This knowledge is vital to the design of research projects and clinical trials to evaluate better treatment strategies. The study also is enrolling uninfected women at high risk for HIV infection, providing data on the risk factors for infection and on the effectiveness of initiatives to prevent HIV infection in women.

HIV-infected women give birth to about 7,000 babies each year in the United States, and approximately 25 percent of these infants become infected with the virus before or during birth. Recently, investigators demonstrated that AZT given to HIV-

infected pregnant women can reduce by two-thirds the risk of transmission of HIV to their newborns. Further study will help determine the risks and benefits of the treatment beyond these encouraging early results.

Each year, an estimated 10 to 12 million Americans acquire an STD other than HIV disease. Approximately 65 percent of these infections occur in people under 25 years of age, with 3 million cases among teenagers. These infections, which frequently occur without symptoms, are often unknowingly passed to others and can cause serious complications, especially in women as well as in children born to infected women. Moreover, the risk of becoming infected or infecting others with HIV is much higher when someone has another STD such as herpes, syphilis, gonorrhea or chlamydial infection.

Because of the urgency of the STD epidemic, initiatives to prevent and control STD's are a key priority of NIAID. Important progress is being made in the areas of vaccines, diagnostics, therapy, behavioral interventions and other methods that promise to facilitate the prevention of STD's and HIV infection.

Recently, NIAID-funded research has led to simple tests for vaginitis and chlamydial infection. NIAID scientists have also developed an experimental vaccine for chlamydial infections that shows promise in laboratory tests. Such a vaccine has the potential to reduce the more than 4 million chlamydial infections that occur each year and the associated costs, which exceed \$2.4 billion annually.

NIAID is also funding research to test the potential of microbe-killing chemicals that could be used in the vagina to protect women from STD's, including HIV, and prevent the spread of STD's to their sexual partners.

Partly because of the HIV epidemic, the health threat posed by TB has resurfaced; since 1985 the number of active cases in the United States has risen by 20 percent. In response to the resurgence of TB, NIAID has formulated a comprehensive research agenda. Priorities include studies on the basic biology of the disease as well as initiatives to develop new and improved TB vaccines, better diagnostic tools, new and improved drug treatments, and improved modes of drug delivery.

The rapid diagnosis and successful treatment of TB are vital for both the patient's welfare and for limiting the development and spread of drug-resistant strains of the organism. In the past year, researchers supported by NIAID reported an experimental technique that holds promise for speeding the diagnosis and ultimately the treatment of TB.

Lyme disease is another growing threat to the Nation's health. More than 9,000 cases were reported in the United States in 1992, up from only a few hundred prior to 1984. In NIAID laboratories and at grantee institutions, scientists are intensively studying the bacterium that causes Lyme disease and how it interacts with the immune system to thwart the body's defenses and cause disease. This basic research is essential to developing improved diagnostics, treatments and vaccines.

Researchers have shown that vaccines based on a Lyme bacterium surface protein can protect mice from infection; several of these vaccines are in various stages of clinical trials. Investigators also have identified a number of immune-activating proteins from the bacterium, with an eye toward improving the accuracy of existing diagnostic tests for acute and chronic Lyme disease. Recently NIH-sponsored researchers have used a sensitive technique called polymerase chain reaction (PCR) to detect the bacterium in joint fluid, providing a method to confirm whether a patient's arthritis is the result of active Lyme infection that could be treated with antibiotics.

Chronic fatigue syndrome [CFS] is a puzzling illness characterized by unexplained, debilitating fatigue, flu-like symptoms, and cognitive complaints. Earlier this year, NIAID investigators reported that CFS patients have higher proportions of certain white blood cells bearing markers indicative of chronic stimulation; hypotheses to explain this observation are currently being tested. Investigations at NIH also suggest that a hormonal imbalance may help explain the lethargy associated with CFS. A study is now under way to determine if low-dose hydrocortisone can restore the hormonal levels to normal and alleviate CFS symptoms.

For many of those affected with kidney failure and other chronic diseases, the transplantation of an organ or tissue is not only life-saving but, when successful, restores a good quality of life to patients. However, immunologic rejection of organs is a major barrier to successful transplantation. An important area of study focuses on ways to improve upon the currently available methods for treating and preventing rejection, which cripple the entire immune system and make the patient susceptible to infection and cancer. Scientists have shown, in monkeys, that it is possible to induce donor-specific tolerance so that the animals can tolerate transplanted kidneys without the need for lifelong treatment with immunosuppressive drugs. Such studies may have clinical applications in human transplantation.

Allergies, which affect 40 to 50 million Americans, are the sixth leading cause of chronic disease in the United States. Major scientific discoveries by NIAID-supported scientists have contributed significantly to our understanding of allergic disease, including asthma, and have led to substantially better methods of diagnosing and treating them. NIAID-funded scientists were the first to identify the IgE antibody that is the key to the allergic response, and have now identified the complex structure of the receptor on allergy-causing cells to which IgE antibodies attach. The receptor provides a promising target for drugs that might block allergic reactions at their outset.

Despite our best efforts to prevent and control infectious diseases and immune disorders, changes in microbes and our environment will surely present new challenges. The speed with which new and improved vaccines, diagnostic tests, drugs and other measures can be developed will depend on our understanding of the human immune system and the ever-growing array of pathogenic invaders that threaten human health. With today's knowledge and modern technologies at our disposal, extraordinary advances in disease prevention are possible. NIAID's continued investment in biomedical research, from basic science to clinical trials and behavioral studies, will provide important benefits to the health of this and future generations.

Mr. Chairman, the fiscal year 1995 budget request for this Institute is \$542,864,000. I will be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. ANTHONY S. FAUCI

Born: December 24, 1940, Brooklyn, New York.

Education: College of Holy Cross, 1962, A.B.; Cornell University Medical College; 1966, M.D.

Professional history: 1966-67, Intern, Department of Medicine, New York Hospital-Cornell Medical Center; 1967-68, Assistant Resident, Department of Medicine, The New York Hospital-Cornell Medical Center; 1968-70, Clinical Associate, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases [NIAID], National Institutes of Health [NIH], Bethesda, Maryland; 1970-71, Senior Staff Fellow, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland; 1971-72, Chief Resident, Department of Medicine, New York Hospital-Cornell Medical Center; Instructor in Medicine, Cornell Medical College; 1972-74, Senior Investigator, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland; 1972-present, Consultant in Infectious Diseases, The National Naval Medical Center, Bethesda, Maryland; 1974-80, Head, Clinical Physiology Section, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland; 1977-84, Deputy Clinical Director, NIAID, NIH, Bethesda, Maryland; 1980-present, Chief, Laboratory of Immunoregulation, NIAID, NIH, Bethesda, Maryland; 1984-88, Clinical Professor, Department of Medicine, Division of Rheumatology, Immunology, and Allergy, Georgetown University School of Medicine, Washington, D.C.; 1985-88, Clinical Professor, George Washington University School of Medicine and Health Sciences, Washington, D.C.; 1988-94, Director, Office of AIDS Research, NIH, and Associate Director of NIH for AIDS Research, Bethesda, Maryland; 1984-present, Director, NIAID, NIH, Bethesda, Maryland.

Board certification and military service: American Board of Internal Medicine, June 21, 1972; American Board of Allergy and Immunology, March 1, 1974; American Board of Infectious Diseases, October 15, 1974; U.S. Public Health Service, July 1968-June 1970, July 1972-Present.

DRUG RESISTANT BACTERIA

Senator HARKIN. In addition, there has been a spate of stories lately, one in Newsweek or Time, and then a lot of other publications in the popular press, about the increase in infectious diseases due to drug-resistant bacteria and others that have come about. I asked Dr. Lee the other day, is there something to this, and he said yes, there was.

Dr. FAUCI. Well, there is something to this, something that looms straight at us both in AIDS and non-AIDS, and that is the emergence of multiple drug-resistant tuberculosis, which is a problem of

extraordinary magnitude in this country and of mind-boggling potential worldwide.

One-third of the world's entire population is infected with tuberculosis, not sick with it but infected, and there are about 4 million people worldwide who are doubly infected with TB and HIV. And the immunosuppression of HIV stands a good chance of bringing out the latent TB that they have in them.

We see now in this country the emergence of multiple drug-resistant strains. So if you just look at TB alone, you are talking about a truly substantive problem. Then when you go back and look at other microorganisms, the same thing is going to happen with staphylococcus and the pseudomonas and all the other organisms that affect people, for example, who are in immunosuppressive regimes for cancer and what have you.

It is a serious problem.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Fauci.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Question. Please describe your Institute's current level and kinds of research on Chronic Fatigue Syndrome [CFS].

Answer. NIAID has an active CFS portfolio of intramural and extramural research activities. Support for CFS totaled \$3.8 million in fiscal year 1993. Our Intramural Research Program is conducting studies aimed at the delineation of clinical, neuroendocrine and immune features of the syndrome. In our Extramural Program, we are supporting several grant projects that focus on prevalence, diagnosis, case definition issues, laboratory and clinical markers (including viruses), natural history, prognosis, cognitive impairment and physiologic response to exertion.

Within our three CFS Cooperative Research Centers, in-depth studies of CFS patients, compared with patients who have better-defined medical disorders, are steadily leading to a more comprehensive understanding of the diverse factors that interact in the expression of the syndrome. Center investigators are looking for possible defects in basic physiologic processes that may help explain the biologic basis for CFS symptoms. The CFS Cooperative Research Centers program has established an extremely valuable computerized database of standardized information on well characterized CFS patients. In addition, the sera and white blood cells of these patients are being stored for future studies.

Question. What is the status of your Institute's plans to begin phase III trials of an AIDS vaccine?

Answer. Since clinical trials of only the most promising vaccine candidates can be supported by the NIAID and because volunteers are a precious resource, careful selection of candidate vaccines to be entered into clinical trials is necessary. In April, NIAID will conduct a thorough assessment of the two products currently in phase II testing. At that time, NIAID, in conjunction with a Vaccine Working Group of government and non-government scientists and community representatives, will decide if the data warrant initiation of a NIAID-supported domestic phase III trial with one or both of the products currently in phase II trials based on developed guidelines. Given the current rate of progress of these and other candidates in the pipeline, we anticipate that one or more phase III trials could be initiated by 1996.

The development of a safe and effective vaccine to prevent HIV infection and/or modulate disease is of high public health importance. Significant progress has been made in the development and clinical testing of potential candidate vaccines and novel adjuvants. In the absence of validated correlates of immunity in humans, it is impossible to develop rigid criteria for moving potential vaccine candidates into pivotal phase III efficacy trials. However, data are needed to judge whether a vac-

cine candidate has a reasonable expectation of being effective prior to entry into a pivotal efficacy trial.

At the present time, it is anticipated that a graded priority would be afforded to candidate vaccines, based on an analysis of supportive scientific and clinical data. Factors to be considered critical in a decision on when to initiate efficacy trials include: safety, as demonstrated in phase 1 and phase 2 human trials; scientific rationale, immunogenicity, protection in animal models; feasibility of a trial because of size and endpoints required; community impact and support; industry support; and the available resources, both financial and volunteer pool.

QUESTIONS SUBMITTED BY SENATOR REID

Question. The NIH Revitalization Act requires " * * that appropriate individuals with expertise in Chronic Fatigue Syndrome or neuromuscular disease * * * are appointed to appropriate National Institutes of Health advisory committees and boards." Has anyone with Chronic Fatigue Syndrome expertise been appointed? If so, which boards and committees have you identified as "appropriate?"

Answer. NIAID has worked with the Division of Research Grants to identify scientists with appropriate expertise for the CFS Special Emphasis Panel, the NIH advisory committee chartered to review CFS research grant proposals. Experts in medicine, virology, immunology, neurology, epidemiology, muscle physiology and statistics are among those who have been invited to serve.

Additionally, the Secretary of Health and Human Services has approved our nomination of Ms. Orvalene Prewitt, co-founder of the National Chronic Fatigue Syndrome Association located in Kansas City, Missouri, to sit on NIAID's National Advisory Allergy and Infectious Diseases Council. Ms. Prewitt brings to the Council her expertise in the areas of health policy, public policy and management. She has also worked extensively in the public sector to educate the community through presentation and written materials about CFS. Her knowledge of the needs in the field of CFS will complement the scientific expertise of other Council members in immunology, virology, microbiology and infectious diseases.

Question. Please explain what kind of intramural and extramural projects NIH has funded thus far to find a cause and/or cure for Chronic Fatigue Syndrome.

Answer. Since patients often report that their CFS followed a "flu-like" illness and NIAID investigators and others have found patterns of white blood cells in patients that are similar to patterns seen in persons acutely infected with viruses, we have supported many studies to look for infectious disease associations. We have also had blood specimens from patients and control group participants stored frozen here in our Intramural Program laboratory and at our CFS Cooperative Research Centers that will be available for comparing their associations with new infectious agents as they become recognized. NIAID recently funded a new project which will systematically use state-of-the-art viral detection methods to examine peripheral blood cells and body secretions to see if a causative agent can be identified. NIAID also is supporting another study to characterize a putative new retroviral agent that was isolated from a CFS patient by one of our grantees. We are making this effort to find an etiologic agent, despite the fact that the epidemiology of sporadic cases of CFS does not suggest a transmissible cause. Other NIAID investigators are examining the possibility that a virus, like human herpes virus-6 [HHV-6], although not a cause, might play a role in illness manifestation or serve as a marker for CFS.

Besides looking for infectious disease associations, we are actively trying to identify immunologic, physiologic and neuroendocrine factors that might help to explain CFS.

Question. What promising areas of research have you found regarding Chronic Fatigue Syndrome that are worthy of investigating next year?

Answer. One of the most interesting new areas of research concerns the differences that exist between the immune and neuroendocrine systems of men and women. Some of these immunologic differences have recently been reported by an investigator supported by NIAID who is studying CFS. A better understanding of these differences may help us to design reproducible immunologic studies and to understand why CFS is three to four times more common in women than in men.

Neurophysiologic studies of sleep patterns, muscle response patterns and respiration being conducted at our CFS cooperative research centers are providing new insights about the effects of the illness and may provide clues about the disease process. Distinctive neuroendocrine patterns of CFS patients, first identified here at NIH, have been confirmed in experiments at one of our CFS cooperative research centers. Continuation of research to determine the clinical relevance of these findings is of high priority.

Finally, our studies to determine why CFS patients respond so badly to physical exertion are providing new information about cytokine responses in CFS patients. This has turned out to be a very promising area of research that we want to continue.

Question. Who determines the priorities for Chronic Fatigue Immunodeficiency Syndrome [CFIDS]-related funding each year? Have any small grants been made available through the small grants program at NIH to some of the scientists pursuing promising areas for scientific inquiry on CFIDS? If so, how are these moneys distributed?

Answer. CFS research priorities are reviewed internally by each Institute with an interest in CFS and their recommendations are made to the NIH CFS Coordinator, who prepares a report that is circulated first to the NIH CFS Coordinating Committee, then to the Director of NIAID (as lead Institute in CFS research) and, finally, to the Director of NIH for approval. To assist them in establishing priorities, last year the NIH CFS Coordinating Committee invited representatives of major constituency organizations to present their suggestions. The NIH Coordinator, a member of the NIAID Executive Committee, also receives input from NIAID's intramural and extramural investigators, including CFS Cooperative Research Center directors.

We do not use the small grants program because of the limitations it poses for research funding. We favor the use of the regular NIH research project grant mechanism for all studies regardless of size and are issuing an announcement to encourage its use for developmental and pilot CFS research projects. We do recognize the need for being able to fund quickly, promising new leads, and we have built into our CFS Cooperative Research Center program a mechanism for the rapid funding of small pilot projects. These projects are reviewed first at the grantee institution and then by the Scientific Coordinator for the CFS Center Program at NIAID. To date NIAID has supported ten pilot projects utilizing this mechanism.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF MARVIN CASSMAN, M.D., ACTING DIRECTOR

PRIORITIES WITH ADDITIONAL FUNDING

Senator HARKIN. Dr. Cassman, Acting Director of the Institute for General Medical Sciences.

Dr. CASSMAN. Thank you for the opportunity, Senator.

The General Medical Sciences Institute is the basic research Institute. We put the bulk of our resources into two areas: Investigator-initiated research, which are individual research grants, and research training.

Additional funds of the kind you request would allow us to do a number of things. In the research grant arena, as others have already stated, we could increase both the support level and the number of grants funded. This would increase the percentage of grant applications that we would be able to fund. And apart from the reasons that have been mentioned already, that is, that there are a great many outstanding applications beyond the level which we can currently pay, I think there is another reason that you may be particularly interested in.

Our advisory council recently recommended that 5 percent of our competing research grant budget be set aside, a maximum, to support applications of unusual promise, but which also carry some risk. Now, why do these grants have to be supported uniquely? Why are they not supported, if they are so promising, through the normal process?

The answer is not that they do badly, but that given the current funding circumstances, they do not do well enough. They fall just beyond the funding level. The reason for this is that, because they carry risk and because the other grants which the review groups see before them are so good, any application where there is a possibility that it may not work, where there is a but; this is an outstanding application but; but the investigator may not be qualified; but the experiments may not work; but that hypothesis may be wrong—these buts translate into a lower priority score and a consequent inability to fund. This is very damaging to the progress of science.

The great physicist, Richard Feynmann, once said in the last years of his life—he was talking to a group of young physicists—that it is important that we do not all follow the same fashion, and in order to do that we have to convince people to take some risks.

That is what we at NIGMS are hoping to do, and if we had the additional funds that probably would not be necessary. These people would already be within the funding range.

NEW INITIATIVES

In addition to expanding our funding in our existing broad areas of basic research such as genetics and structural biology, we would also, I think, start a number of new initiatives. As you know, the General Medical Sciences Institute had a considerable degree of involvement in the initiation of the revolution in the biotechnology industry, and many of these new initiatives, I think, would be directly supportive of that industry.

One of these new areas which you have already heard about is structure-based drug design. Dr. Varmus mentioned Captopril in his introduction, which was an early example of a drug developed through structure-based drug design. This is an area that is now on the verge of enormous possibilities since the tools and technologies are being developed so rapidly.

There are at least six new biotechnology companies that have been formed in recent years specifically to exploit this technology, in addition to all of the pharmaceutical companies that are investing heavily in this area.

The problem is that we do not quite know how to do this yet, and furthermore there is a great difficulty in that, when you develop a drug to inhibit a compound in a test tube, that does not mean it is a drug; it just means it is an inhibitor. In order to be a drug, it has to work in the body, it has to get to where it is aimed at. And we really do not know how to achieve those goals yet.

BIOAVAILABILITY

This whole issue of bioavailability is one that we have examined in a recent workshop, and it is one where I think the fundamental basic properties of the physiological system that allow drugs to go to their targeted location is one that needs to be further examined. There are other areas, such as protein engineering and biomolecular engineering, which I think are new evolving areas in which we would like to initiate new programs.

These are all in the embryonic state, but they're poised to make rapid progress if funds become available.

In the research training area, we have a particular interest in supporting underrepresented minorities and bringing them into the biomedical research enterprise process. We have in the last year or so generated a new umbrella program called the Minority Opportunities in Research, MORE Program. This encompasses both our minority access to research careers [MARC] research training program and our Minority Biomedical Research Support [MBRS] Program, which supports minority researchers and research institutions.

PREPARED STATEMENT

A new director for this program, Dr. Clifton Poodry, is coming on board in the next month and we hope to have some funds available for him to generate new initiatives. But obviously, these will be limited by the existing stringency of the budget.

I do not want to add, I think, anything more about the FTE situation. Everyone who has already spoken has said, I think, everything I could say. Thank you.

[The statement follows:]

STATEMENT OF DR. MARVIN CASSMAN

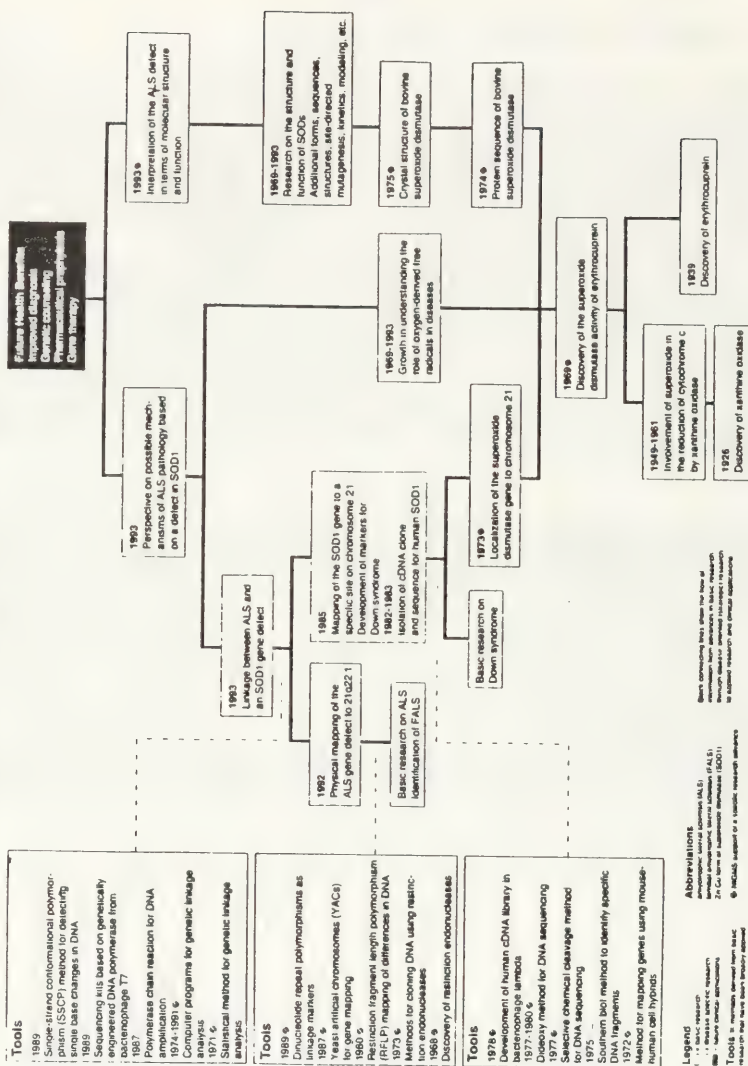
Mr. Chairman, and members of the committee, good morning. I am pleased to come before you to present the programs and progress of the National Institute of General Medical Sciences [NIGMS].

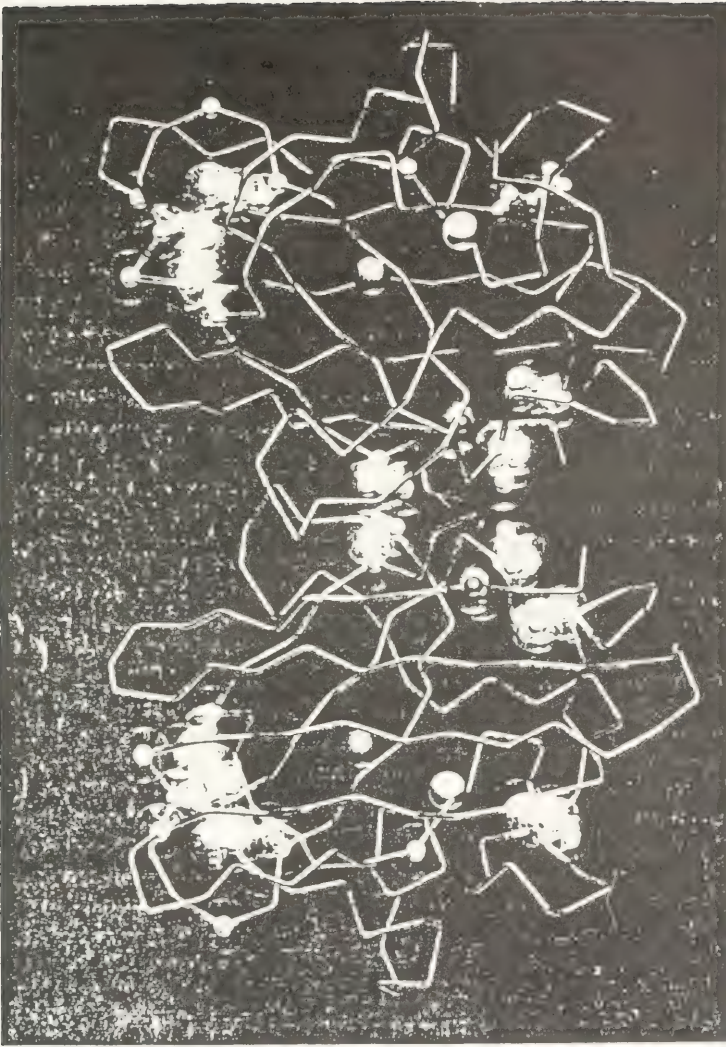
As you have heard on a number of occasions, the basic research supported by NIGMS lays the foundation for a broad range of disease-targeted studies. It also supplies the biotechnology and pharmaceutical industries with the steady stream of new knowledge they need for continued growth and vigor.

The past year has been an exciting one for basic research. Not only were many fundamental discoveries made, but the basic research roots of a number of important clinical advances were readily apparent. It is now clearer than ever that a single basic research finding can fan out into applications in many areas, and that a major clinical advance generally builds, pyramid-style, on years of basic research results. Stated another way, the results of basic research are certain to have practical applications in the future, often the very near future. The more fundamental a finding, the broader its application is likely to be. What cannot be predicted is what disease a given discovery will apply to, or what discovery is needed in order to learn more about a given disease.

BASIC RESEARCH AND ALS

Today, I would like to show you several examples of how years of NIGMS-supported basic research have resulted in stunning advances in our understanding of specific diseases. The first example is amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig's disease. It was a little more than one year ago that scientists announced the discovery of a gene involved in a hereditary form of this disease. To their surprise, the gene turned out to encode an enzyme called superoxide dismutase [SOD], which was identified in 1972 by an NIGMS grantee doing basic studies on oxygen in biological systems. Over the next two decades, as outlined in the attached chart, NIGMS supported much of the fundamental acquisition of knowledge about the SOD enzyme that placed scientists in a position to apply the knowledge quickly once the link to ALS was made. If researchers had waited until a specific gene was shown to be involved in ALS before doing fundamental research on the enzyme the gene encodes, it might have taken another 10 to 20 years to get where we are today.





bent Out of Shape: Structural Distortions in Superoxide Dismutase Linked to ALS

This computer graphics figure shows the structural location of mutations in the enzyme superoxide dismutase, which has been linked to the devastating neurological disorder amyotrophic lateral sclerosis (ALS). The most common mutations are shown in red; others are shown in gold. These mutations alter sites important for the enzyme's stability and assembly, rather than its activity.

When the connection between ALS and SOD was discovered, scientists did not know how a defect in the enzyme could lead to the devastating neurological symptoms of the disease. So they turned to structural biology for answers. Two NIGMS grantees at the Scripps Research Institute, Drs. John Tainer and Elizabeth Getzoff, had been studying the structure of the SOD enzyme for many years. They rapidly determined where mutations occurred in people with ALS, and found that the mutations disrupt the place where two SOD molecules join together to form an active enzyme. As a result, SOD is less able to perform its job of scavenging harmful forms of oxygen, called free radicals. When free radicals build up, neurological damage occurs.

The contribution of structural biology to providing a clue to the origin of ALS underlines one of NIGMS' guiding principles—that studies of biological structures at the molecular level will provide important clues to their function, and will point the way to new means of disease diagnosis, treatment, cure, or prevention.

Beyond its support of research on SOD itself, NIGMS also supported the development of a number of tools and techniques that were critical to research on both SOD and ALS. These same tools enabled researchers to track down genes involved in other diseases, such as Huntington's disease, cystic fibrosis, muscular dystrophy, and some types of cancer.

BASIC RESEARCH AND CANCER

Similar charts could trace the fundamental underpinnings of many other major clinical advances. For example, the discovery of a gene involved in a form of colon cancer—announced last December to great media attention—depended on years of NIGMS-supported basic research on how bacteria and yeast repair errors in DNA copying. The scientists who conducted this research wanted to know more about how cells work, but they realized that their studies would shed light on conditions, like cancer, in which cells do not work properly. What they could not predict at the outset was exactly how their results would be applied, but there was no doubt that there would be important applications.

Another case of years of basic research coming together to yield important new insights about disease is found in the story of p53. This protein plays a key role in half of all human cancers, including those of the breast and colon, as well as in the normal cell cycle of growth and division.

NIGMS grantees made many contributions to an understanding of p53's function. These were largely the result of studies of the cell cycle in such model organisms as frog eggs and yeast, which helped establish a link between cell cycle control and cancer.

We now know that under normal circumstances, p53 acts as a tumor suppressor by turning on the production of another protein, which keeps healthy cells from dividing prematurely. However, when the p53 gene is mutated, the stage is set for uncontrolled cell division and the development of cancer. In recognition of the tremendous surge in p53 research, *Science* magazine named p53 its 1993 Molecule of the Year.

As a *Science* editorial on p53 noted, "The great excitement in this field and the understanding that has already been obtained are typical of basic research. A rather innocuous molecule is shown to play a key role in a basic body function. No possible clarification of its important role could have been obtained without the background knowledge of biochemistry, cell biology, and genetics that was also the product of basic research * * *. Soon the diagnostic opportunities that basic research has made available will enable clinicians to diagnose certain cancers at a stage early enough for effective intervention to take place. Therapeutic drugs are likely to follow."

BASIC RESEARCH AND DRUG DEVELOPMENT

NIGMS also supports research at the forefront of drug development. Some scientists, such as Dr. Marvin Caruthers of the University of Colorado at Boulder, are pursuing rational drug design as an alternative to the current method of screening massive numbers of compounds for activity against a target molecule. Rational drug design builds upon basic knowledge in cell biology, genetics, biochemistry, and especially structural biology. It offers particular promise in the development of new drugs to fight AIDS.

A second area of exciting research is the design of tiny, hollow structures that can hold drugs, transport them to a site in the body, and release their contents. Dr. Julius Rebek of the Massachusetts Institute of Technology has created one such structure, which has the distinction of being self-assembling. He took his inspiration from viruses, which have evolved a similar mechanism for inserting their genetic mate-

rial into a cell. Dr. Rebek's team is now working on developing a switch to open the hollow structure under certain conditions.

A different type of switch has been devised by another NIGMS-supported chemist, Dr. Stuart Schreiber of Harvard University. This switch could refine gene therapy by enabling patients to take a nontoxic pill to turn an inserted gene on or off—or, if the gene malfunctions, to destroy it. The approach might allow gene therapy methods to be used for diseases that are treatable with therapeutic proteins—such as insulin for diabetes—since it would allow the regulation of proteins produced in the body by genetically modified cells. This new technology is still at the test-tube stage, but it is causing great excitement and has already been licensed by a biotechnology company.

NOBEL RECOGNITION

A final example of the broad applicability of NIGMS-supported research is found in the Nobel Prize. NIGMS has compiled a remarkable record of supporting scientists for work that later wins the Nobel Prize. The most recent round of prizes was no exception: NIGMS provided research or training support to all four of the winners of prizes in chemistry and physiology or medicine. The work honored by the prizes—the discovery that genes are interrupted by noncoding sequences and the development of two important research tools, the polymerase chain reaction and site-directed mutagenesis—has truly advanced scientific knowledge and revolutionized the way in which research is done.

TRAINING TOMORROW'S SCIENTISTS

NIGMS helps our country maintain its scientific advantage by training many of the scientists who will conduct research in the future. These scientists require somewhat different training than was needed in the past. They need broader exposure to a variety of disciplines, to enable them to capitalize rapidly on new findings in many areas. These scientists are different in other ways, as well. More of them are female, and more of them are members of minority groups that have traditionally been underrepresented in biomedical research. NIGMS is committed to increasing the number of minority scientists and strengthening the research capabilities and science curricula of institutions with substantial minority enrollments. The Institute has placed major emphasis on its Minority Opportunities in Research Programs Branch, and I am pleased to announce the recent appointment of the first director of this branch, Dr. Clifton Poodry. Dr. Poodry, who is a Native American, has been a faculty member at the University of California, Santa Cruz since 1972. He has been deeply involved in programs to increase the recruitment of minorities to science careers, as well as in science education and research in the field of developmental genetics.

AN INVESTMENT IN THE FUTURE

In conclusion, I would like to quote from an article in the July 1993 issue of the *Journal of NIH Research*, written by Dr. Keith Yamamoto of the University of California, San Francisco, and Elizabeth Marincola, Executive Director of the American Society for Cell Biology. They state that "a strong and unswerving commitment to fundamental research is not the best way to guarantee continued progress in human medicine—it is the only way." I hope that my remarks today have reinforced this point—that basic research plays an important role in the health of the Nation and in technology development, and that it is one of the best investments we can make in our future.

Mr. Chairman, the fiscal year 1995 budget request for the National Institute of General Medical Sciences is \$882,189,000. I would be pleased to answer any questions that you might have.

BIOGRAPHICAL SKETCH OF DR. MARVIN CASSMAN

Position: Acting Director, National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

Birthplace and date: Chicago, Illinois, April 4, 1936.

Education: B.A., University of Chicago, 1954; B.S., University of Chicago, 1957; M.S., University of Chicago, 1959; and Ph.D., Albert Einstein Medical School, 1965.

Experience: Acting Director, NIGMS, NIH, 1993-present; Deputy Director, NIGMS, NIH, 1989-present; Director, Biophysics and Physiological Sciences Program, NIGMS, NIH, 1985–89; Senior Policy Analyst, Office of Science and Tech-

nology Policy, 1985–86; Staff, House Subcommittee in Science and Technology Policy, 1982–83; Chief, Molecular Basis of Disease Section, Cellular and Molecular Basis of Disease Program, NIGMS, NIH, 1978–84; Health Scientist Administrator, Cellular and Molecular Basis of Disease Program, NIGMS, NIH, 1975–78; Assistant Professor, University of California, Santa Barbara, 1967–74; NIH Postdoctoral Fellow, University of California, Berkeley, 1965–67; and Research Fellow, Northwestern University Medical School, 1959–61.

Association memberships: International AIDS Society; American Association for the Advancement of Science; and Biophysical Society.

Special awards or citations: Presidential Meritorious Executive Rank Award, 1991; Senior Executive Service Award, 1990; Senior Executive Service Award, 1989; Senior Executive Service Award, 1988; Senior Executive Service Award, 1987; NIH Director's Award, 1983; and NIH Quality Increase Award, 1980.

Committee memberships: NSTC Committee on Fundamental Science, 1994; PHS Human Radiation Studies Working Group, 1994; NIH Tuberculosis Executive Committee, 1993-present; NIH Task Force on the Commercialization of Intellectual Property Rights from NIH Funded Extramural Research, 1993-present; NIH Bioengineering Working Group, 1993-present; NIH Intramural Research Infrastructure Subcommittee, 1993-present; Chemical and Engineering News Advisory Board, 1993-present; NSF Advisory Committee on Biological Sciences, 1993-present; Chemical and Engineering News Advisory Board, 1993-present; NSF Advisory Committee for Biological Sciences, 1993-present; Shannon Awards Committee, 1991-93; and NIH AIDS Executive Committee, 1987–93.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

This is extremely interesting.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RECENT DISCOVERIES

Question. Can you offer us some examples of very recent discoveries made by NIGMS grantees that have been picked up by biotechnology or pharmaceutical companies because of their significant promise?

Answer. The NIGMS played a major role in the development of the biotechnology industry, and continues to play an active role in this arena, since the industry feeds on NIGMS-supported basic research discoveries. Several recent examples demonstrating this follow:

- Structure based drug design, an approach to drug design intended to more closely target the suspected biological factor in a particular ailment, has attracted the interest of at least six new biotechnology companies, as well as other well-established pharmaceutical firms.
- Basic research supported by NIGMS identified inhibitors which have proved to be effective therapeutic agents against some enzymes called topoisomerases, which are involved in various forms of cancer. Three pharmaceutical companies are currently attempting to develop new anti-cancer agents based on these inhibitors.
- Very recently, NIGMS grantees developed synthetic receptors capable of turning genes on and off at will. His development has already been licensed for development by a biotechnology company. This field of research could have major implications for human gene therapy.
- NIGMS grantees discovered that carbohydrates may play an important role in wound healing. Some biotechnology companies are now attempting to synthesize novel variants of these carbohydrates to facilitate the wound healing process. This could have enormous financial implications by shortening hospital stays, and reducing the number of days an employee loses to sick leave.

Question. Your general statement mentioned that the Institute has “initiated a program to fund research in new and underexamined areas of science” in an effort to “ensure a greater degree of diversity in the Institute’s grant portfolio.”

Can you elaborate on this program and what its goals are?

Answer. Our Advisory Council recently recommended that we set aside up to five percent of our research dollars to fund competing applications that were of unusual novelty and promise, but that also had enough risk attached to them that they might not be in the competitive funding range. It was the Council's feeling that applicants, reviewers, and the Institute as well, are too conservative in the choice of research problems. This is because the difficulties in obtaining research support generate pressure on applicants to submit and on reviewers to approve for funding "safe" applications, or proposals which have a high degree of assurance of success. While these highly meritorious applications deserve most of our support, it should not be at the exclusion of funding more adventurous, diverse proposals. The great physicist Richard Feynman once said, "It is very important that we all do not follow the same fashion. So it is necessary to increase the amount of variety * * * and the only way to do it is to implore a few guys to take a risk * * *." By encouraging the funding of more diverse applications, NIGMS is trying to make it a little easier for applicants to take that risk. This is a pilot program, and we will be monitoring it closely.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
STATEMENT OF DUANE F. ALEXANDER, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Alexander, Director of the National Institute of Child Health and Human Development.

Dr. ALEXANDER. Thank you, Mr. Chairman. As with my colleagues, much of the emphasis in spending an increase of the proportion you are talking about would be on supporting investigator-initiated research grants both in basic and applied areas. This would cover the scope of our Institute's activities, ranging from infant mortality to birth defects research, mental retardation, infertility research, behavioral development, and health behaviors, as well as medical rehabilitation.

PREPARED STATEMENT

Perhaps the most exciting thing about this increase would be that it would send a signal to investigators in the field, particularly young scientists, that the downward spiral we have seen in success rates in recent years for grant applications was at an end, and that we would reverse it. The 40-percent success rate that we had in the past, that declined to 30, to 20, and below, was now going to go back up again, and there was a bright future for them in research.

[The statement follows:]

STATEMENT OF DR. DUANE F. ALEXANDER

The mission of the National Institute of Child Health and Human Development [NICHD] is to assure that every individual is born healthy, is born wanted, and has the opportunity to fulfill his or her potential for a productive life unhampered by disease or disability. To fulfill this goal, the NICHD conducts and supports laboratory and clinical research on the reproductive, developmental, and behavioral processes that determine and maintain the health and well-being of children, adults, families, and populations. In addition, research in medical rehabilitation is supported to maximize the function of individuals with physical disabilities resulting from diseases, disorders, injuries or birth defects.

Some of the most exciting advances from the NICHD research program this year benefit our very youngest patients: newborn babies. For example, NICHD-supported scientists developed and tested a new drug that effectively prevents the development of jaundice in infants. The drug, called tin mesoporphyrin [SnMP], blocks the production of bilirubin, the yellow pigment that leads to severe jaundice when it builds up in the blood faster than the liver can process it. This drug is a simple, safe, rapid and inexpensive therapy to curb neonatal jaundice, the most commonly treated medical condition in preterm and fullterm newborns. This jaundice (hyperbilirubinemia) can lead to deafness and mental retardation if not rapidly controlled. The usual treatment is several days of intensive exposure to special lights, known as phototherapy. This involves an extended hospital stay. With this new therapy, a single, small dose of SnMP shortly after birth eliminates the need for phototherapy in most infants. In the U.S., about 250,000 infants each year develop jaundice severe enough to warrant phototherapy treatment. This new drug thus can alleviate a cause of both medical and parental concern and save health care dollars as well.

NICHD intramural scientists have pioneered an innovative technique for performing surgery on babies still in their mother's womb. This new procedure uses long, thin tubes, about the size of a pencil lead in diameter, inserted through the mother's abdomen to perform delicate surgery on malformed or otherwise at-risk fetuses. Previously, surgery on the unborn required a large incision in the mother's uterus and posed great risk for both mother and child. Very few of these earlier attempts were successful. This new technique minimizes the risk. As the investigators gain more experience and train others to utilize this procedure, their technique will greatly increase our access to the fetus for diagnosis and treatment.

The obstetricians who developed this technique are part of the Institute's new Perinatal Research Branch, established recently as a result of a Congressional directive and located in the District of Columbia. Research achievements such as this advance should greatly contribute to our understanding of fetal development and the management of high risk pregnancies. This understanding is essential to solving the persistent nationwide problem of infant mortality.

The NICHD, in conjunction with other Federal agencies and private sector organizations, is about to embark on a major public education campaign to influence infant sleep position. Evidence indicates that infants who sleep on their back or side are at reduced risk for Sudden Infant Death Syndrome (SIDS), the leading cause of infant death after one month of age. It is thought that if a change in infant sleep position from abdomen to back or side can be wrought in the U.S., the SIDS rate will drop as a result.

Birth defects are another leading cause of infant mortality. A long search for the genes that determine the pattern of early embryonic development succeeded this year. NICHD-supported scientists discovered several of the genes that direct the process of initial formation of the nervous system and limbs in mice and fruit flies. Identifying these genes, termed "hedgehog genes", represents a major advance in developmental biology. Study of their action, both normal and abnormal, should provide significant clues to the origin of birth defects in humans.

As mandated in the NIH Revitalization Act, the NICHD recently awarded a grant to support the first comprehensive national study of the determinants of adolescent health. The study will show what influences contribute to the development of behaviors that affect health, such as alcohol or tobacco use, seat belt or helmet use, exercise, or sexual behavior. Some 160 middle and high schools and 19,000 students and their parents will be involved.

Between 35 and 43 million Americans have one or more conditions that limit their life activities. The NICHD's National Center for Medical Rehabilitation Research is taking advantage of remarkable advances in bioengineering and applying them to enhancing the independence and quality of life of persons with physical disabilities. Projects include the development of computer software to aid in the proper fitting of artificial limbs, the design of an electronic implant to convey sensation in artificial limbs, and the development of a high quality, robotic arm for below-elbow amputees. Other NCMRR-sponsored projects in the prosthetics/orthotics field include efforts to improve the knee joints of prosthetic legs and the gripping mechanisms of prosthetic hands, and to improve the orthoses currently used to correct the gait of children with cerebral palsy.

Women's health is a major focus of NICHD research. Scientists we supported are making progress toward elucidating the biology of endometriosis, a poorly understood condition that affects about 10 percent of U.S. women of reproductive age. These investigators have found that a significant number of endometriosis patients have abnormalities of a class of proteins called integrins. Since integrins are a family of proteins involved in cell attachment and invasion, they may prove to have a role in the process by which uterine cells implant and grow in inappropriate sites as endometriosis lesions, as well as in the infertility associated with the disease.

The NICHD, as part of its AIDS research program, has been working for several years to develop and test female controlled barrier contraceptives, as well as spermicides that would also be microbicidal. Such products would protect against both pregnancy and sexually transmitted diseases, including HIV infection. The fiscal year 1995 budget request includes funds to expand this initiative, which is being conducted in concert with the National Institute of Allergy and Infectious Diseases. It will allow us to expand basic research on vaginal physiology and immunology and develop new, improved products and test them as quickly as possible through NICHD's soon-to-be-established Contraceptive Testing Network. We will also study the behavioral factors that affect the acceptability and effective use of female-controlled barrier contraceptives and spermicides.

With a portion of the additional AIDS funds requested, NICHD will expand a national research effort on adolescent AIDS. One quarter of all reported AIDS cases

involve young adults 20 to 29 years of age, and there are data to indicate that an increasing number of individuals are being infected with HIV as teens.

In another collaborative AIDS effort, NICHD helped design and fund the large clinical trial in which zidovudine [AZT] therapy reduced by two-thirds the risk of transmission of virus from HIV-infected women to their babies. The results of this trial were so compelling that the trial was terminated early so that AZT can be offered to all pregnant women as soon as possible. Although this treatment did not protect all the babies in the study, the results are very promising. We are now testing whether the addition of hyperimmune anti-HIV globulin to AZT treatment in pregnancy can further reduce HIV transmission to the fetus, with the hope of ending pediatric AIDS.

These are just a sampling of the many NICHD research highlights for this past year and plans for fiscal year 1995. All contribute to the betterment of our nation's health, particularly that of its mothers and children, and have the added benefit of saving health care dollars as well. Mr. Chairman, the NICHD requests \$516,736,000 for fiscal year 1995. I would be glad to answer any questions.

BIOGRAPHICAL SKETCH OF DR. DUANE FREDERICK ALEXANDER

Birth: August 11, 1940, Baltimore, Maryland.

Marital status: Married Marianne Ellis, Washington D.C., June 23, 1963; two children.

Education: Pennsylvania State University, University Park, Pennsylvania, B.S. Degree, Pre-Medical, 1962; Johns Hopkins University School of Medicine, Baltimore, Maryland, M.D. Degree, 1966.

Internship: Intern and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1966-67.

Residency: Assistant Resident and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1967-68.

Military service, 1968-1970: Surgeon (LCDR), U.S. Public Health Service, and Clinical Associate, Children's Diagnostic and Study Branch, National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), Bethesda, Maryland; 1971-Present: From Surgeon to Assistant Surgeon General, U.S. Public Health Service.

Fellowship: Fellow in Pediatrics (Developmental Disabilities), John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child, Johns Hopkins Hospital, 1970-71.

Licensure: Maryland Board of Medical Examiners.

Certification: Diplomate, American Board of Pediatrics, 1973.

Positions held: 1971-74, Assistant to the Scientific Director, NICHD, NIH, Bethesda, Maryland; 1974-78, Medical Officer (Staff), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW; 1978-82, Assistant to the Director, NICHD, NIH; 1982-86, Deputy Director, NICHD, NIH; and 1986-present, Director, NICHD, NIH.

PROGRAM INCREASE

Senator HARKIN. Are you below 20 now?

Dr. ALEXANDER. We are right about 20 percent, yes. And our intent would be to bring that success rate in our Institute up to between 45 and 50 percent.

Our programs in clinical trials in maternal-fetal medicine, in neonatology, in sudden infant death syndrome, in reproductive medicine, and women's health would all be increased. We have protocols in these areas that are queued up waiting for available funds to start them, and this would give us a wonderful opportunity to expand that activity.

Our activities in contraceptive development, which have basically been level, would finally be able to take off. We have a number of promising new leads to pursue in that area that this infusion of funds would enable us to do. We have directives from the Congress to establish an intramural perinatal research branch in the District of Columbia, which we have done; and an intramural gynecology

research program, which we have done. But they are basically staffed with skeleton crews because of FTE problems as well as funding problems.

The increase in funding would allow us to expand these programs to meet the congressional intent if we were able to do something about the FTE problem. No FTE's have been provided for these new programs, nor for the new National Center for Medical Rehabilitation Research that the Institute has established, again as the result of a congressional directive.

All these programs have been established at a time during which we have lost 70 FTE's. So they have had to obtain FTE's at the expense of other NICHD programs, at a time when even those are shrinking.

Establishing a new extramural program in an area new to the NIH, medical rehabilitation, is very personnel intensive because you are working with investigators who are not used to the NIH system and who require a lot of staff attention if they are to succeed. So we are doing the best we can in that area. We are proud of what we have accomplished but it is another indication of the way that FTE restrictions cramp our style and inhibit our ability to fulfill research plans and do the things that the Congress and the American people expect us to do.

Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AIDS AZT STUDY

Question. The Committee was very pleased to hear of the recent preliminary finding that zidovudine [AZT] reduces the rate of transmission of the HIV virus from infected pregnant women to their babies. Please tell us more about the results of this study.

Answer. The purpose of this study was to determine if the rate of transmission of HIV from pregnant infected mother to child could be reduced by giving the mother Zidovudine [AZT] during her pregnancy orally, during labor intravenously and to her baby for six weeks after birth. The study targeted otherwise healthy HIV-infected pregnant women who did not require AZT therapy for their own health, who had not received AZT therapy during this pregnancy (over 95 percent had no prior AZT therapy), and who had CD4 counts above 200. After studying only 364 mother-infants pairs, it was determined that AZT administered in this fashion to this group of HIV-infected women would reduce the risk of transmission of the AIDS virus by 68 percent—from 25.5 percent to 8.3 percent.

Virtually all new cases of pediatric HIV infection come from mother to child transmission. Now we can markedly decrease this transmission in certain groups of women (e.g., healthy infected women without prior AZT therapy and with an intact immune system). Of course, accomplishing this remarkable reduction assumes that these infected pregnant women can be identified early in their pregnancies and that they and their babies can be treated with the same regimen used in the study.

Question. What has been the NICHD involvement in this trial?

Answer. NICHD staff worked on the design, implementation, and execution of the study and its analyses. NICHD provided 15 of the 50 U.S. sites and about a quarter of the patients enrolled in this study. In addition, NICHD staff have worked on the design and implementation of a study, which provides long-term follow-up of the in-

fants born to infected women enrolled in this study, to evaluate the potential risk of long-term toxicity of this treatment. NICHD is also providing the leadership for a PHS Task Force which will deal with the complex issues of interpretation and application of these study results, especially with regard to screening pregnant women for HIV infection. Finally, NICHD continues to work on the design and implementation of other strategies, particularly in more severely infected women, to further decrease the number of cases of pediatric AIDS. Our goal is to see HIV/AIDS disappear as a disease of children.

RESEARCH CENTERS

Question. What plans does the Institute have to fund new research centers in perinatal research and developmental disabilities?

Answer. Early this year, the NICHD issued requests for applications [RFA's] for a new center in perinatal research to respond to the special needs of rural populations and a new developmental disabilities research center. The application receipt dates for both RFAs are in May 1994 with initial reviews scheduled in July and Council review in September. Depending upon the scientific merit of the applications received as determined by peer review, awards will be made prior to the end of the fiscal year.

Question. At what level will existing NICHD research centers be supported in fiscal year 1994 and fiscal year 1995?

Answer. In fiscal year 1994, existing centers will be supported at approximately the fiscal year 1993 dollar level. The fiscal year 1995 request will provide for an overall increase to existing centers of about 5 percent.

NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

Question. What progress has been made by the new National Center for Medical Rehabilitation Research? What are some of the problems hampering further development of this center?—such as the reductions in staffing?

Answer. In its first 2½ years, the National Center for Medical Rehabilitation Research [NCMRR] funded 46 research projects and co-funded or reimbursed funds to support 20 other projects originating outside of the NICHD. The NCMRR welcomes its cooperative ventures as they provide a means of increasing the amount of research activity that is consonant with its priorities. The NCMRR has also sponsored six major scientific conferences and numerous workshops on topics directly related to the health care of people with disabilities. These meetings have been especially productive, for they have brought together scientists from a variety of disciplines that have not addressed the health care needs of people with disabilities. The result has been an increased interest by the scientific community in the health care issues faced by people with disabilities.

Progress has been made in several areas through work supported by the Center.

Training.—Twenty universities are training a new generation of scientists to conduct multidisciplinary research in medical rehabilitation.

Assistive devices.—A variety of assistive devices have been developed through the Small Business Innovation Research program. One investigator has invented a device that allows people who use leg prostheses to feel the position of their feet. This is accomplished by transmitting the stimulation generated by pressure on the prosthesis on the ground to the remaining portion of the leg(s). A software product is being developed to allow individuals with mobility impairments to view barriers, slopes and contours of trails they may wish to explore when they visit National Parks. An inexpensive adjustable back support for people who use wheelchairs has been developed that will improve the user's comfort and posture.

Women's health issues.—There is little information available regarding the impact of the disabling process on sexuality in women with disability. The Center funds a demographic survey instrument that will be used to measure sexual functioning in women with physical disabilities and to evaluate the impact of psychological, social and environmental factors on women's abilities to enter into successful personal relationships. This study addresses a current gap in disability-related research and addresses behaviors that are taken for granted by women without disabilities such as dating, physical intimacy, marriage and parenting.

Men's health issues.—In order to develop appropriate therapeutic strategies to improve fertility in men with physical disabilities, the NCMRR is supporting studies to identify pathologies of the male reproductive organs associated with spinal cord injury and to develop clinical interventions that will enhance sperm fertility.

Biomaterials.—The Center is supporting ten exploratory studies to modify biological products that can be used to stimulate the regeneration of tissues and to supply the gene products necessary to maintain function or reduce the process of further

injury. Results from this research will lead to the development of coating materials that can be used on implanted devices such as indwelling catheters or electrodes to render them biocompatible and to reduce infection. Other projects will develop implantable or cutaneous biosensors to detect pressure and skin breakdown in order to decrease the incidence of pressure sores.

Neurorehabilitation.—Development of therapeutic interventions that will lead to the recovery of function after injury to the nervous system is dependent on characterizing long term changes in synaptic plasticity. The NCMRR is supporting studies that are examining changes in functional innervation after spinal cord injury and examining the relationship between improved neurological function with pharmacological and physical therapy interventions.

While much progress has been made, the pursuit of additional research opportunities has been somewhat delayed due to the overall need for fiscal restraint and hiring restrictions. Important areas of opportunity include pediatric rehabilitation, management of chronic pain associated with physical disability, assessment and treatment of muscle fatigue associated with long term impairment (polio, spina bifida, spinal cord injury, etc.), treatment effectiveness of rehabilitation treatments in general, health issues of women with disabilities, recovery of function from traumatic head injury, and assistive device (prostheses, orthoses, environmental modifications, wheelchair safety, etc.) development. Many of these initiatives would greatly benefit from a multidisciplinary approach that combines the expertise of both fundamental and clinical scientists.

QUESTIONS SUBMITTED BY SENATOR BOND

Question. At the National Institute of Child Health and Human Development, as funding for pediatric AIDS is redirected to the new Office of AIDS Research, does this alter your ability to expand research funding for other priority areas?

Answer. The consolidation of the AIDS budget in the NIH Office of AIDS research will not affect the overall direction and funding of other non-AIDS research activities.

BIRTH DEFECTS

Question. How will those priorities be refocused and which, if any, of those efforts will relate directly or indirectly to research into birth defects.

Answer. While NICHD will not refocus its research goals as a result of consolidation of the AIDS budget, the prevention and treatment of birth defects remains a high priority to the Institute. Basic research and innovative new technology in this area are providing new avenues to knowledge needed for effective therapy and prevention. Genes that are developmentally important and relevant to human disease are now being identified and characterized through animal models combined with human studies. Ongoing research is defining how genetic cascades regulate cell proliferation, cell differentiation, cell interactions and cell fate. The roles of environmental agents and nutritional factors are also being investigated. These studies can provide a systematic approach to understanding the networking of genes and gene families, the mechanisms of development, the determination of critical developmental periods and the identification of genetic and environmental miscues that give rise to such conditions as neural tube defects and skeletal abnormalities. The knowledge gained through these activities serves as a basis for instituting preventive programs.

NATIONAL EYE INSTITUTE
STATEMENT OF CARL KUPFER, M.D., DIRECTOR
BUDGET REQUEST

Senator HARKIN. Dr. Kupfer, Director of the National Eye Institute.

Dr. KUPFER. Ever since the establishment of the National Eye Institute in 1970, we have put our money into investigator-initiated research, so our highest priority with increased funding would be to have a success rate of about 50 percent for these types of grants.

We would look in terms of program toward at least three areas that are rapidly emerging. The first has to do with the finding of the chromosome where the gene for at least one type of glaucoma has now been found. I think this opens up the entire field of glaucoma, which affects about 3 million Americans at the present time and accounts for the second cause of blindness in older adults.

The second opportunity which is ripe for rapid development is in the lens, especially with the concept of what brings about an opacity in the lens, a so-called cataract. With this new concept, one of the proteins in the lens acts as a chaperone and protects the other proteins from becoming opaque. I think there are now hypotheses that can be tested experimentally to determine what role this may play in the formation of cataract.

At the present time there are about 1½ million cataract operations a year. It accounts for 12 percent of part B of Medicare. In the next decade and a half, this number will increase to about 3.5 million cataract operations a year, so the economic impact of this is considerable.

The third area where we would want to put our resources is in the area of retinal degeneration. Again, as you have heard, molecular genetics is moving very rapidly ahead and we now have a model of retinal degeneration which is ready for development of gene therapy.

The remaining funds would then go to clinical trials, gene therapy being at the top of our list. I think, again, we really want to move as rapidly as we can in this area, because I think in terms of therapy, much of the prevention of disease will lie in this particular area.

There are two other areas where we would put our resources. One is the National Eye Health Education Program. We are reaching out to the patients with diabetes, to individuals who may be at high risk for glaucoma, namely African-Americans, and now we want to expand that to bring in the Hispanic population, a group at very high risk for complications of diabetes.

The last area is health services research. Again, as has been mentioned before, I think NIH has to position itself with respect to health care reform and we would like to begin to expand our re-

search activities in terms of measurement of quality of life, economic analyses of new forms of treatment, and finally to assess quality of care by actual online assessment of what is happening in the offices of ophthalmologists around the country.

FTE REDUCTION

The impact of FTE's: I would just like to briefly say that we have proportionately the smallest number of people administering our extramural research grant program, so that any cuts in FTE's must come from our intramural program, and that is a particular hardship. We are going to have about a 11-percent decrease in personnel.

If I may take 2 minutes more, sir, I would just like to say that this year we are celebrating our 25th anniversary. The entire focus of that is to give the American public—the taxpayers—a stockholders' report on what their resources, that have been given to the Eye Institute research community, have accomplished in the last 25 years.

PREPARED STATEMENT

I think we have a very good story to tell and I want to tell it to the public. The scientists speak to each other; they know what is going on. But I know we have a responsibility for the public and of course for the Congress to know that.

There will be a gala April 13 in Union Station and an exhibit called "Vision," which will again demonstrate to the public what accomplishments have been made in the last 25 years.

Thank you, sir.

[The statement follows:]

STATEMENT OF DR. CARL KUPFER

Mr. Chairman, I am pleased to report that the NEI is now in the first year of its sixth long-range plan. As I have mentioned in previous years, the NEI places a premium on strategic planning to identify future needs and opportunities in vision research. I would like to share with the Committee some of the initiatives that are now underway as a result of this national planning activity and some recent findings that our previous planning efforts have helped to facilitate.

Historically, the NEI has sought to invest its resources in areas that appear ready to yield rapid advances. This was the rationale for our investigations in the 1970's on the use of laser surgery as a treatment for diabetic retinopathy. It was reported this year that this treatment now saves the Federal government between \$1.2 and \$1.6 billion annually.

Through our recent planning process, the NEI has identified glaucoma research as one of several areas of great opportunity. Glaucoma, which affects three million Americans and is particularly prevalent among African Americans, damages the optic nerve and is often associated with increased pressure at the front of the eye. During the past several years, glaucoma researchers have produced important new epidemiologic data, state-of-the-art diagnostic techniques, and improved medical and surgical treatments.

But this progress must be followed up. To seize this opportunity, the NEI recently launched three large clinical trials on glaucoma. These studies will produce objective, scientifically validated information on the disease's natural history, risk factors, diagnosis, and treatment. We anticipate that this investment will provide practitioners with improved strategies for patient care and could eventually save the Federal government millions of dollars in disability-related payments.

The NEI also recognizes that glaucoma's prevention, diagnosis, and treatment will only be enhanced with an improved understanding of the disease process. I am pleased to report that NEI-supported basic research on glaucoma yielded some promising leads last year. One group reported that a novel neurotransmitter lowers

the pressure in the eye. This finding now opens the door to a possible new therapeutic approach to reduce pressure and prevent optic nerve damage. Other NEI-supported researchers determined the chromosomal location of a gene responsible for a form of juvenile glaucoma. This is the first glaucoma-causing gene ever mapped. Although the link between juvenile-onset glaucoma and the more prevalent primary open-angle glaucoma needs further elucidation, this development could lead to greater understanding of the disease process.

Another excellent research opportunity is the role of vitamin/mineral supplements in the treatment of cataract and age-related macular degeneration [AMD]. By the year 2030, more than 66 million Americans will be at risk for these common eye diseases of aging. If an easily administered, daily vitamin/mineral supplement could protect people from these diseases before more rigorous and costly therapy is required, it would have enormous public health implications.

To investigate this possibility, the NEI has launched the Age-Related Eye Diseases Study [AREDS], a multi-center clinical study and trial involving 4,400 older Americans. The AREDS will provide patients and practitioners with the most definitive information yet regarding the safety and effectiveness of this possible treatment.

The NEI continues to investigate other promising strategies to prevent age-related eye diseases. In the early 1980's, there were fewer than 250,000 cataract operations performed each year in the United States. In less than 15 years, this number has jumped to more than 1.5 million cataract surgeries per year at a cost exceeding \$5 billion. Reimbursement for cataract surgery now accounts for 12 percent of the Medicare Part B budget. I must add that by the year 2030, there will be a need for 2.3 million cataract surgeries per year, a demand that will be extremely difficult for any health care system to meet.

However, if cataract development could be delayed by just 10 years, the need for cataract surgery would decrease by almost half. One way to delay cataract is to develop drugs that act to slow down the disease process. The NEI is now supporting several studies on the study of drugs that counteract oxidative damage, which is thought to be an important factor in cataract development.

I am also pleased to report this year that NEI-supported scientists reported recently that most adults with retinitis pigmentosa [RP] should take a daily 15,000 IU vitamin A supplement. This recommendation is the first from a well-designed clinical trial demonstrating that the 100,000 Americans with this blinding retinal disease can be treated. However, the scientists also found that high-dose vitamin E supplements appeared to cause the disease to progress more quickly. Prior to publication of these findings, the NEI issued a "Dear Colleague" letter to approximately 36,000 eye care professionals nationwide that prepared them for future consultations with their RP patients. Retinitis pigmentosa research is now among the most productive areas of basic vision research. With the recent explosion in biotechnology, scientists can now isolate a defective, RP-causing gene by studying blood samples from families with a history of the disease. Such studies already have led to the discovery of more than 40 mutations in several retinal genes that are responsible for several forms of RP. The scientific opportunities to develop clinical strategies for early diagnosis, genetic counseling, and treatments, such as gene therapy, are now well within reach.

This year, the Diabetes Control and Complications Trial reported that people with diabetes who tightly controlled their blood glucose levels greatly decreased their chances of having the eye, nerve, and kidney complications of diabetes. Unfortunately, many people with diabetes will not escape the complications of the disease. Complementary approaches are now needed to help protect the health of people with diabetes.

For this reason, the NEI continues to develop drugs that inhibit the enzyme aldose reductase, which has been linked to the eye and nerve complications of diabetes. NEI intramural researchers are developing new aldose reductase inhibitors using biochemical, pharmacological, and computer design techniques. These new drugs are needed to eliminate the side effects and improve upon the first generation of aldose reductase-inhibiting drugs. Recently, the NEI and the Juvenile Diabetes Foundation International initiated a \$4 million cooperative program to stimulate basic research on the cellular and molecular basis of diabetic retinopathy.

The NEI is also making important strides in understanding disorders involving the processes by which visual signals are sent to the brain. In the visual system, there is a precise pattern of connections between the retina at the back of the eye and the brain. This pattern is established and refined during early life. Scientists have shown recently that certain chemical signals are needed at the right time and place for infants to develop normal vision. Determining the nature of these signals may lead to new treatments to repair developmental abnormalities, such as crossed

eye and lazy eye. As many as 5 percent of Americans now have crossed eye, lazy eye, or abnormal visual processing.

Research on myopia, or nearsightedness, which affects 25 percent of Americans, has moved ahead very rapidly in the laboratory. Scientists have learned a great deal about what seems to control the size and shape of the eye, since an eye that is too large causes most myopia. How generalizable this information will be to humans is still unclear. But, for the first time, researchers are designing experiments to test these theories and to determine whether nearsightedness is preventable.

I am pleased to report the NEI-coordinated National Eye Health Education Program is making excellent progress in expanding its activities to alert Hispanics about diabetic eye disease, a leading cause of preventable blindness in this group. The NEHEP has also recently supported a two-year pilot program to increase eye health education among African Americans in Durham, North Carolina and Cleveland, Ohio.

The NEI also continues to study the possible causes of dry eye, which affects millions of middle-aged and older women. The institute sponsored a workshop last year and is actively encouraging the submission of research grant applications to investigate this condition.

Mr. Chairman, the fiscal year 1995 budget request for the National Eye Institute is \$292,022,000. I will gladly answer any questions that the Committee might have.

BIOGRAPHICAL SKETCH OF DR. CARL KUPFER

Born: February 9, 1928, New York, New York.

Education: A.B., Yale Univ., 1945-48; M.D., The Johns Hopkins Medical School, 1952; Certified, American Board of Ophthalmology, 1958.

Professional history: Internship and Assistant Residency, Wilmer Eye Inst., Johns Hopkins [JH] Hospital, 1952-54; Lab. Asst., Biostat., JH School of Medicine, 1953-58; Research Fellow in Ophth., Harvard Medical School, 1958-60; Instructor in Ophthalmology, Harvard Medical School, 1960-62; Assistant Professor of Ophthalmology, Harvard Medical School, 1962-66; Prof. and Chairman in Ophth., Univ. of Washington School of Medicine; Research Affiliate, Univ. of Washington Primate Ctr., 1966-70; Director, National Eye Institute, 1970-present; Acting Deputy Director for Intramural Research, NIH, 1991-92.

Professional organizations: American Physiological Society; Association for Research in Vision and Ophth.; Am. Academy of Ophthalmology; American Ophthalmological Society; Pan Am. Ophth. Society; Johns Hopkins Univ. Soc. of Scholars; Member, Inst. of Medicine, National Academy of Sciences.

Honors and awards: The Secretary's Special Citation, DHEW, 1972; The Superior Service Award, DHEW, 1974; Presidential Rank Award of Meritorious Executives, 1983; Migel Medal, Amer. Foundation for the Blind, 1976; Public Service Award in Ophth., Amer. Academy of Ophth. and Otolaryngology, 1977; Special Award of Honor, The Assn. for Research in Vision and Ophthalmology [ARVO], 1983; David Rumbough Memorial Scientific Award, JDF, 1983; The Lighthouse Pisart Vision Award, 1984; Cavera Medal of Univ. of Rome, 1985; The Mildred Weisenfeld Award for Excellence in Ophth., 1987; Presidential Distinguished Rank Award, 1991; Statesmanship Award, Joint Commission on Allied Health Personnel in Ophthalmology, 1991; Lions Clubs Intl. Humanitarian Award, 1992; Kupfer Award of the ARVO, 1993; Leadership Award, AOS, 1993; Benjamin F. Boyd Humanitarian Award of the Pan-Am. Assn. of Ophthalmology, 1993; Joslin Diabetes Center-MediSense Award, 1994.

EXCIMER LASER

Senator HARKIN. I was at an eye institute in southern California where they were using lasers to reshape the eye so you did not have to wear glasses any more. I forget what that is called.

Dr. KUPFER. Photorefractive keratectomy.

Senator HARKIN. I remembered that, but I did not remember the name of the institute. Then I read an article about it being done in Russia. Is that something that is gaining more popularity? It sounds very unique to me if they could actually do this.

Dr. KUPFER. Well, I think radial keratotomy has been with us 10 or 15 years in the United States and, as a matter of fact, we are

finishing a 10-year followup study on patients who have had radial keratotomy, and I think on the basis of those findings we will know whether this is the way to go. Perhaps there are other techniques using laser to overtake radial keratotomy in reshaping the cornea.

Senator HARKIN. I think the one I saw in California was something else.

Dr. KUPFER. Photorefractive keretectomy, yes. That is with the laser beam that actually removes micron layers of tissue from the cornea and reshapes it. I think that was at the University of Southern California.

Senator HARKIN. Exactly, that is where it was. It was not radial keratotomy, it was something else.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NEI 25TH ANNIVERSARY

Question. This is the 25th Anniversary of the National Eye Institute. What would you list as some of the NEI's greatest accomplishments?

Answer. There are a number of important accomplishments which should be mentioned. These include: the development of an increased national focus on research on blinding eye diseases and the special problems of individuals who are blind or visually impaired; the development and implementation of a series of national strategic plans for vision research; the landmark clinical trials of cost-effective treatments for diabetic retinopathy and other eye diseases which set a high standard for modern clinical vision research and have moved the entire field forward; the unraveling of the molecular basis of how the eye responds to light and transmits visual signals to the brain; outstanding visual neuroscience research which has led to an understanding how the visual system develops and how we "see"; the discovery of gene defects in several forms of retinitis pigmentosa and the initiation of gene therapeutic approaches; the establishment and a strong intramural research program and a well-managed, highly-efficient extramural research program; and establishment of the National Eye Health Education Program.

EYE CARE TECHNOLOGY FORUM

Question. I understand that the NEI has developed a Government/Academia/Industry Forum on accelerating progress in developing cures for eye disease. What are the goals and objectives of this forum?

Answer. The Eye Care Technology Forum, as it is called, serves as a mechanism to foster integration along the basic research to eye care service continuum. This is being accomplished through interaction and exchange of ideas among individuals from industrial corporations, university researchers, and governmental officials from agencies such as the National Eye Institute and the Food and Drug Administration. It is believed that this integration will advance the discovery, development and distribution of new technology-based products and services of increased therapeutic effectiveness and lower cost.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF KENNETH OLDEN, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Olden, Director of the National Institute of Environmental Health Sciences.

Dr. OLDEN. Thank you, Mr. Chairman.

Our Institute originated in response to public concern about environmental cancer. So naturally most of the programs in the Institute focus on carcinogenesis. But it is clear that the American people expect us to also address those diseases and dysfunctions other than cancer.

With a 50-percent increase in budget, we would be able to do that. For example, reproductive dysfunctions, premature birth, neuroendocrine disorders, pulmonary dysfunctions, osteoporosis. There are a whole host of human diseases and dysfunctions that the environment either causes or exacerbates, and there is considerable pressure on our Institute from Members of Congress and the American people to begin to address those diseases in addition to cancer.

So we clearly need the resources to do what I think is the mission of the Institute. In addition, our Institute provides more than 50 percent of the data used to drive risk assessment decisions in this country, and I would say that most of the science that is needed to make intelligent risk assessment decisions simply is not in place. So what we would like to do is to develop programs to strengthen the risk assessment policies of this country.

Let me just mention—I will not go into any detail—what is needed. The regulatory agencies are asking for—and it is very clear that risk assessment decisions could be improved by—a knowledge of mechanisms. In addition, we typically have to extrapolate from animals to humans. We have to extrapolate from high doses to low doses. Mechanistic data would improve that. We need to develop new methodologies, new models to improve that extrapolation.

For example, we need to improve our capacity to do predictive toxicology, and we can do that now with improvements in computational chemistry, in computer sciences. There are something like 68,000 chemicals in commercial use in the United States today; 1,500 more are introduced every year. So it is going to be impossible to test all of those at a rate of 8 to 10 per year, the rate that we have been doing ever since the toxicology program was created in 1978.

So obviously we have got to use the new developments in molecular biology, computational chemistry, analytical chemistry, to improve our capacity to make predictions, and in fact we can do that. But we need to put our resources there and get the best minds in

the country to help us advance the science of predictive or functional toxicology.

The other area that we need to push and advance is molecular prevention/intervention. Basic science knowledge in environmental health sciences now has advanced tremendously. There are a lot of opportunities now to develop molecular medicine prevention/intervention strategies, and we need to do that.

Historically, environmental health sciences had focused on behavioral modification. In other words, we identified an environmental hazard, we passed that information on to the regulatory agencies. They regulated it and modified or controlled our behavior. However, there are environmental agents that we cannot get out of our environment overnight. Lead is one of them, dioxin is another example.

So the issue is how do we deal with those environmental agents that it is going to take us years to eliminate even if we had the resolve and the resources to address them and we had the know-how to prevent some of these diseases. Aflatoxin-induced liver carcinogenesis is another example for which we are now on the verge of developing an intervention.

We need human studies. Human studies have been absent from our environmental health research. There were no human studies, except epidemiology, and in most of those cases they were descriptive in nature, they were not molecular. So we now need human studies.

And if you have human studies, extrapolations from animals to humans will be unnecessary. In some cases it is timely and we have the information that we can move from animals to humans, and we need to do that. And we have started those programs, but it takes resources.

The other area is susceptibility. The regulatory agencies, EPA, regulate on the assumption that the difference among individuals in the population is at most tenfold. Well, we know that is not true. There are dramatic differences, thousands of fold differences, in individual susceptibility. And the susceptibility I am talking about is to environmental exposures.

We need to understand the breadth of that diversity. We need to look at subpopulations. Children, for example, are not miniature adults; they are children. Their biology is very different and they are clearly more susceptible to some exposures, for example pesticides, than adults. Senior citizens are more susceptible. Among different ethnic groups, there are going to be differences in susceptibility, and we are beginning to define these.

Finally, we need to understand the relationship between poverty, malnutrition, and susceptibility to environmental exposure.

PREPARED STATEMENT

These are areas I think our Institute has not made the kind of investment I think the American people want and also the kind of investment I believe is important to the health of the American people as it relates to the environment.

Thank you, Mr. Chairman.

[The statement follows:]

STATEMENT OF DR. KENNETH OLDEN

From conception to death, humans are exposed to a multitude of environmental agents, including foods and nutrients, physical agents such as heat and ionizing and non-ionizing radiation, social and economic factors that affect our health and behavior, lifestyle choices and substance abuse, and synthetic and naturally occurring chemicals. The mission of the National Institute of Environmental Health Sciences [NIEHS] is to determine how these environmental exposures affect our health, how individuals differ in their susceptibility to these effects, and how these susceptibilities change with age. To fulfill this mission, the Institute must provide the science necessary to understand the impact of the environment on human health, must translate this information into prevention and intervention strategies and must communicate this information to the American people.

Opportunities now exist for the NIEHS to capitalize on improved techniques in molecular biology and computational chemistry to unravel the mechanisms by which environmental agents perturb normal biological processes. This more mechanistic approach will be used to improve human risk assessment and to develop prevention or intervention strategies. Risk assessment decisions form the basis of Federal, State and local laws and regulations which require the expenditure of billions of dollars to reduce potentially harmful human exposures. NIEHS has targeted five areas of emphasis as critical to the risk assessment process: basic biology of environmental disorders; hazard identification and characterization; molecular prevention and intervention; development of alternative methods; and environmental justice.

Basic biology of environmental disorders.—To date a large part of environmental health research has focused on identifying the environmental causes of diseases. Future research promise lies in understanding the actual molecular and genetic basis of environmentally caused disorders.

Good health depends on the proper functioning of genes which control cellular growth, differentiation and death. When critical genetic material is altered, the functions over which it exerts control can go awry, leading to birth defects, cancer, neurobehavioral abnormalities, and other diseases and dysfunctions.

Human health also depends on a complex network of chemical signals between cells. The molecules that transmit these signals are primary targets of toxic substances in the environment. Identification of the role of individual protein messengers and receptors in cellular determination, growth, differentiation, and responsiveness, and understanding the ability of environmental chemicals to interact with these critical proteins is an important NIEHS research priority. Research in this area holds promise for defining the roles that environmental agents may play in a host of diseases and dysfunctions, including infertility, birth defects, neurological disorders, immune dysfunctions, and chronic diseases.

The variation in individual response to environmental agents is exceptionally wide. This variation is accounted for by differences in metabolism, DNA repair capacity, or genetic predisposition to specific diseases. It is because of this large diversity in responsiveness to environmental toxicants that risks to environmental agents have been difficult to pinpoint, particularly at low exposures. Opportunities now exist for studies of genetic susceptibility for cancer and other diseases in which an environmental component can be presumed.

Of particular interest to the NIEHS are environmental components of women's, children's, and minority health. Environmental factors contribute to many of the disease processes that are specific to, or predominate in, women. For example, heavy metals have been shown to accelerate osteoporosis, a bone disorder affecting most women over age 60. A number of widespread environmental toxicants such as DDT and PCB's mimic the female hormone estrogen and could play a role in hormonally related cancers such as those of the breast, uterus, and ovaries. Environmental estrogens could also be important components of benign proliferative disorders of the female reproductive tract, such as endometriosis and uterine fibroids. Many environmental compounds affect reproduction, leading to infertility, spontaneous abortion, or birth defects.

Similarly, children's health is also a priority of the NIEHS. The developing fetus and infant represent particularly vulnerable targets for environmental agents. An adverse effect sustained at this time can cause health problems throughout an individual's life. These problems may not even be apparent until many years after the original exposure.

Finally, greater emphasis has been assigned to human studies with the development of a clinical program. The NIEHS has started several new clinical research programs. One multi-center project will examine the efficacy of an oral chelator, succimer, to treat children with low blood lead levels. Another program will use local medical centers to meld their clinical research with the laboratory research on-

going at NIEHS. Initial studies will look at environmental factors that promote asthma, dysfunctions of reproductive endocrinology, and degenerative neurological diseases.

Hazard identification and characterization.—Use of traditional animal testing and epidemiologic studies to identify environmental hazards to human health will remain a cornerstone of the Nation's prevention and intervention program. The strength of these techniques will be greatly improved with incorporation of new insights concerning the molecular basis of toxic effects into animal testing and human epidemiology studies. However, animal studies often provide only descriptive information, revealing the toxicity of an environmental agent by its ability to cause adverse effects such as tumors, histopathologic abnormalities, or genetic changes. An even more meaningful way to relate animal studies to human health effects is by determining the underlying mechanisms leading to toxicity.

Hazard identification is often handicapped by an inability to determine individual exposure levels or to account for individual differences in uptake and distribution of toxicants. As our knowledge of the molecular components of environmental exposures increases, biological indicators measuring both exposures and effects can be developed for use in both epidemiologic and testing studies. Potentially, biomarkers could be used in screening programs for exposed human populations to provide early warning of environmental exposure, predict development of disease, and enable clinicians to prescribe appropriate intervention therapies.

Prevention and intervention.—Further understanding of the environmental components and basic biology of disorders can lead to prevention and intervention strategies to circumvent many adverse health effects. Traditionally these strategies have focused on primary prevention techniques such as eliminating or reducing environmental exposures. These techniques will continue to be important parts of the Nation's environmental health programs. An integral part of this program is the development of the science that will enable risk assessors to determine how much reduction of exposure is needed to protect public health. Generating risk assessment levels relies strongly on rodent data and on extrapolation of results in rodents to probable effects in humans. The relevance and power of these assessment schemes will be greatly enhanced when the biological mechanisms for adverse effects are incorporated into the mathematical models used to estimate risks from low exposures.

As we understand the molecular and cellular basis of environmentally induced diseases, secondary prevention and intervention techniques could be developed to treat people following an adverse environmental exposure. These molecular intervention techniques would rely on manipulations of the biological mechanism underlying environmentally induced diseases, such as activating and inactivating enzymes, receptors, and other molecular components. They would be particularly useful in dealing with environmental exposures that are ubiquitous or difficult to eliminate. They also would have important implications in the pharmaceutical and pesticide industries, which could in the future develop products with maximal effectiveness and minimal side effects based on a structural understanding of underlying biological mechanisms.

Development of alternative methods.—Assessment of the potential adverse health effects of chemicals has been accomplished largely by testing these substances in laboratory animals. While such tests have been useful in identifying human health hazards, improved test methods are needed that are more predictive, that can be achieved in a shorter timeframe, and that are more cost-effective. There is also an expectation from the public that the scientific community will increase efforts to develop new "alternative" methods that will reduce animal use, replace animals with non-animal methods or lower species where possible, and refine animal use to eliminate or further minimize pain and distress.

Research and development efforts will: (1) develop genetically engineered cell lines to characterize the biological activity and toxicity profiles of chemicals at the molecular and cellular level; (2) develop transgenic animals that more closely model the human response to toxic substances; (3) systematically investigate non-mammalian and invertebrate species to identify functional and structural attributes that may be useful as research or testing models; (4) further characterize the similarities and differences between animal testing models and humans to enhance the usefulness of this information in the risk assessment process; and (5) improve computer-based prediction and modelling systems for specific toxicologic endpoints.

Environmental justice.—Environmental justice is a newly emerging social issue. It refers to the fact that where one works and lives is a matter of choice largely dependent upon socioeconomic factors. Intuitively, one would expect that the poor and politically disenfranchised are at a greater risk of living near hazardous waste sites or working at hazardous occupations. For these reasons they would be more likely to suffer from environmentally related diseases than would those in the mid-

dle and upper socioeconomic classes. It is a logical extension of the Institute's mission to explore the dimensions of the Nation's environmental equity problem.

To this end, the NIEHS is presently supporting three environmental justice research centers and a large multi-institutional clinical trial to improve the treatment of lead poisoning. A national conference focusing on environmental justice held in February 1994 attracted more than 1,100 participants.

The main objective of this program is to establish a new research paradigm linking members of the community who are directly affected by adverse environmental conditions with researchers and health care providers. Development of community-based strategies to address environmental health problems requires approaches that are not typically familiar to the research and medical communities. The distinctive needs of individual communities and their inhabitants are often neglected in identifying environmental health problems and devising appropriate medical intervention tactics.

This budget request of \$267,955,000 is adequate to advance the research agenda outlined above. In times of economic constraints difficult choices have to be made; however, I am pleased that environmental research has been identified as a priority for the Nation.

Mr. Chairman, thank you for the opportunity to appear before your Committee. I will be pleased to answer any questions that you may have.

BIOGRAPHICAL SKETCH OF DR. KENNETH OLDEN

Born: July 22, 1938, Parrottsville, Tennessee.

Education: B.S., Knoxville College, 1960; M.S., University of Michigan, 1964; Ph.D., Temple University, 1970 (research done in absentia at the University of Rochester).

Professional history: 1964-65, Research Assistant, Department of Biological Chemistry, Columbia University; 1970-74, Research Fellow and Instructor of Physiology, Harvard University Medical School; 1974-77, Senior Staff Fellow, Division of Cancer Biology and Diagnosis, National Cancer Institute; 1977-78, Expert (Biochemistry) Division of Cancer Biology and Diagnosis, National Cancer Institute; 1978-79, Research Biologist, Division of Cancer Biology and Diagnosis, National Cancer Institute; 1979-82, Associate Director for Research, Howard University Cancer Center, and Associate Professor of Oncology, Howard University Medical School; 1982-84, Associate Director for Research and Deputy Director, Howard University Cancer Center, and Associate Professor of Oncology, Howard University Medical School; 1984-85, Associate Director for Basic Research and Deputy Director, Howard University Cancer Center, and Professor of Oncology, Howard University Medical School; 1985-91, Director of the Howard University Cancer Center and Professor and Chairman of the Department of Oncology, Howard University Medical School; 1991-present, Director, NIEHS and NTP.

Professional organizations: American Society for Cell Biology; American Society of Biological Chemistry; American Association of Cancer Research; Society for Biological Response Modifiers; Metastasis Research Society.

Honors, awards: Porter Development Postdoctoral Fellow, 1970; NIH Postdoctoral Fellow, 1970-73; Macy Faculty Fellow, 1973-74; Citation Classic, Current Contents, Life Sciences, 1980; Member Division of Cancer Biology and Diagnosis Board of Scientific Counselors, National Cancer Institute, 1981-85; Member, Public Policy Committee of the American Society for Cell Biology, 1984; Co-Chairman, Mid-Atlantic Region of National Black Leadership Initiative on Cancer, 1987-89; Member, Board of Directors, Association of American Cancer Institutes, 1987-90; Member, Division of Cancer Treatment Board of Scientific Counselors, National Cancer Institute, NIH, since 1988; Selected as "One of sixteen historical and contemporary role models" for the Museum of Science and Industry exhibit on Black Achievers in Science, Museum of Science and Industry, Chicago, IL, 1988; Member, Board of Directors of Association of Minority Health Professions Schools, 1988-present; Member and Co-Chairman of National Advisory Committee on Socio-Economically Disadvantaged of The American Cancer Society, 1988; Member, Advisory Panel Council for Cell Biology, National Science Foundation, 1989-90; Presidential appointment to membership on the National Cancer Advisory Board, 1991; Associate Editor of Cancer Research, The Journal of the National Cancer Institute, Cell Regulation, and Environmental Health Perspectives.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Very good. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AGRICULTURAL CHEMICALS

Question. Please describe your Institute's research in the area of the health effects of agricultural exposures.

Answer. Under Federal law, studies of the acute and chronic toxicity of new agricultural chemicals must be done by the manufacturer and reported to the Environmental Protection Agency [EPA] for use in the regulatory process. However, up to eighty percent of chemicals now in use were either grandfathered or have been inadequately tested. The health effects of low-level, long-term exposures to mixtures of agricultural chemicals as routinely experienced by agricultural workers and their families or by millions of consumers, are virtually unstudied either in human populations or in animal models.

Farmers tend to live longer and healthier lives than other people. But evidence has shown that they have higher than normal rates of several cancers. These cancers include leukemia, multiple myeloma, non-Hodgkin's lymphoma, and cancers of the brain, prostate, stomach, skin, and lip. This phenomenon may be due in part to farmers' chronic exposure to potentially harmful compounds such as pesticides, chemical solvents, engine exhausts, animal viruses, sunlight, and other substances common to agriculture.

The National Institute of Environmental Health Sciences [NIEHS] supports research which focuses on understanding the effects of pesticide exposures on farmers and their families. These exposures are not limited to application exposures but include exposures through ground water that might be contaminated with pesticides. Also, NIEHS and the National Cancer Institute [NCI] are collaborating on the nation's largest epidemiologic study of farmers and their families. The Agricultural Health study will identify and assess factors that may account for previously reported cancer excesses among farmers. About 100,000 farmers, spouses of farmers, and pesticide applicators will be involved in the study. The research will also assess non-cancer endpoints, such as reproductive and neurologic concerns, that may also be associated with farm practices and lifestyles.

ENVIRONMENTAL HEALTH SCIENCES CENTERS

Question. I understand you recently had to decrease continuation funding support for the environmental health centers because of a shortage of funding, even though you praised the quality of research in that area as "a very important part of our national effort." Can you explain the reasons for this shortfall in funding?

Answer. This year, because of our attempts to open the centers program to greater competition and peer review, we solicited applications which resulted in the award of two new centers for fiscal year 1994. One new center focuses on basic and clinical research that examines the influence of environmental factors on human health and the pathogenesis of disease at both the cellular and molecular levels. The other new center focuses on interdisciplinary approaches to understanding mechanisms by which environmental chemicals impact human health and to identifying factors that effect these mechanisms.

Unfortunately, the addition of these important centers has meant that the other centers have not been able to receive funding-increases and will be funded at approximately the same direct cost which we have provided in recent years.

Question. What will be the impact of this cut on your Institute's research into the environmental factors causing particular diseases?

Answer. I consider the environmental health sciences centers supported by the Institute as an extremely important part of this nation's overall research efforts and I am committed to continuing our support of this effort at a level which would allow us to address a multitude of questions on environmental health. Hopefully, the addition of centers during this time of burgeoning opportunities in the environmental health sciences will help the Institute meet critical research needs.

Question. The fiscal year 1994 Senate report requested from your Institute a report on the decline in funding for environmental health sciences research centers, and the reasons for this decline. Dr. Olden, are you prepared to report on the recent funding history for environmental health sciences research centers?

Answer. The overall appropriation for the NIEHS has declined in constant dollars over the past several years due in part to the Nation's economic status in a given budget year and in part to the Institute's competitive status among the other NIH components. Since investigator-initiated research project grants are the major priority at NIH, other mechanisms of support, including research center grants, may not always receive the desired funding levels. However, in each year since fiscal year 1990, when the NIH cost management plan was implemented, environmental health sciences centers have been funded at or slightly above the prior year's total cost.

QUESTIONS SUBMITTED BY SENATOR BOND

BIRTH DEFECTS

Question. One area that I have spent a great deal of effort is in the prevention of birth defects. That work has centered on public/private efforts to study the causes of infant mortality and birth defects and to find cures or treatment for birth defects when possible. At NIEHS, what specific resources are being committed to research the adverse reproductive outcomes related to environmental contaminants?

Answer. The NIEHS conducts and supports basic and applied research into the causes of adverse reproductive outcomes. These studies are conducted through extramural grants, intramural projects, and research and development contracts at a level approximating \$27 million annually.

Studies include basic cellular research to understand how normal fetal development occurs and how specific environmental exposures perturb this delicate process. Other studies are carried out in laboratory animal experiments and by human epidemiologic studies in populations that have been exposed to individual chemicals or agents.

Examples of recent projects supported run the gamut between in vitro studies to determine the cellular target of pesticides in the male reproductive system to an epidemiologic study investigating the adverse reproductive outcomes associated with exposure to nitrous oxide in dental assistants.

Question. What are the unmet needs for funds in the fiscal year 1995 budget to expand this work and specifically what areas of research should be funded?

Answer. An emerging field in the environmental health sciences related to reproductive health research is known as environmental estrogens. These are compounds that mimic estrogen found naturally in all mammals. These compounds have similar molecular structures to estrogen which enables them to bind to estrogen receptors on cells and set off a chain of events. Environmental estrogens can occur naturally in plants; therefore, diets high in these foods could cause adverse outcomes. There are many environmental estrogens that are manmade such as dioxin and diethylstilbestrol. Exposure to the manmade compounds can come through contaminated drinking water, pesticide residues on foods, and so forth. These compounds have been shown to cause adverse reproductive outcomes in controlled laboratory studies. Some of these compounds have also been implicated as causes of breast and ovarian cancer as well.

Because of the potential high exposure and devastating effects of these agents, much additional research should be performed to determine what effects can be attributed to their exposure and at what level of exposure these effects would be expected to occur.

Question. How are these efforts coordinated with the Centers for Disease Control and Prevention?

Answer. To insure that our efforts are not duplicative of those performed at CDC, last year I instituted annual meetings with the heads of all federal agencies with environmental health science research programs. In addition to these meetings, a representative from the CDC participates as a liaison member of the National Advisory Environmental Health Sciences Council.

NATIONAL INSTITUTE ON AGING

STATEMENT OF RICHARD J. HODES, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Richard Hodes, Director of the National Institute on Aging.

Dr. HODES. Thank you very much, Mr. Chairman.

The responsibility of the National Institute on Aging has expanded as a direct result of the successes you have heard so much about. The success of research funded by various Institutes of the National Institutes of Health over the years has had one common effect in extending lifespan. This has converged to create a kind of a demographic imperative, if you will.

As an example thereof, and only one, Alzheimer's disease, an affliction that we are all well aware of, currently affects approximately 4 million Americans at a cost estimated at \$100 billion, and is predicted to increase to perhaps a four to fivefold level of prevalence on the basis of pure changes in age profile of the population in the absence of intervention.

This creates for all of us a heightened sense of urgency in the research directed toward problems that accrue to an aging population. I would echo and reinforce what a number of Institute directors have already mentioned: Our overall approach is based on the strong conviction that there needs to be an appropriate balance of basic research to understand basic molecular and cellular mechanisms of normal and abnormal biology, coupled with an ability to take advantage of scientific opportunities as they arise, to intervene in specific diseases.

I would like to briefly comment on a number of areas in which the efforts of the Institute would be greatly facilitated by an increase in available resources.

ALZHEIMER'S DISEASE

To continue on the theme of Alzheimer's disease as one example, over the past years efforts have been directed toward trying to identify risk factors, environmental or genetic, as a way to understanding the causes of disease and toward developing opportunities to intervene. In particular over the last few years, I think you have all heard a great deal about the discovery of genetic risk factors.

Initially, risk factors that were identified in relatively small numbers of people, specific families with early onset disease, focused on genes, in particular the gene encoding the protein that is a precursor of beta-amyloid, one of the hallmarks of the disease. In the past year there has been particular excitement about identification of another risk factor, namely a particular allele or form of the ApoE gene.

Surprisingly, it has turned out that in a large number of Alzheimer's disease cases, not the rare familial types but disease that was previously thought of as sporadic, the expression of a certain form of the ApoE gene appears to have associated with it a substantial increase in risk of disease.

I should point out, because I think it is consistent with what Dr. Varmus and other Institute directors have said, that some of these developments come from basic research in unexpected areas. ApoE was first described in research supported by the National Heart, Lung, and Blood Institute out of interest in its role as a transporter of lipids, and, therefore, of great interest to research on atherosclerotic disease.

Now having identified ApoE as a risk factor in a substantial proportion of Alzheimer's patients, the NIA is committed to following this and similar genetic leads in several directions. On the one hand, we need to extend our epidemiologic studies to understand among various populations, such as minority and gender different populations, whether this is a risk factor and how widespread it will be.

The real excitement about identifying risk factors is that they provide opportunities to delve into the mechanism of disease. The Institute would certainly take advantage of increased available resources to concentrate and intensify the efforts to understand the mechanism by which ApoE influences Alzheimer's disease.

It may do so via its lipid transport function. Exciting studies have shown that there is an association between ApoE and its different versions and amyloid protein. There is also evidence that another protein, the tau protein, known from cell biology studies to be important to maintaining the integrity of the skeleton of all cells, including nerve cells, associates differently with different versions of ApoE.

There is great promise and excitement because of the opportunity to pursue basic science and from these basic findings, be poised to intervene genetically or biochemically.

GENE THERAPY

I would echo the theme of gene therapy as an area of interest to the Institute. Among the systems responsible for a great deal of morbidity and mortality in the elderly is the cardiovascular system. We are excited by evidence that shows it is possible to introduce selected genes into the heart or into the blood vessels, genes which influence the formation of new blood vessels when that is needed after the loss of blood vessels by occlusion, or genes which appear to be able to slow or inhibit the occlusion of blood vessels.

For example, after blood vessels in the heart are opened surgically, there is a high rate of renarrowing of the vessels. Gene therapy designed to introduce products that would inhibit this renarrowing is really on the verge of clinical application. We are excited and enthused both about basic research into the mechanisms of effective gene transfer as well as ultimately in their clinical introduction.

PREPARED STATEMENT

Frailty, as generically described, is a problem which can affect older people, and is characterized by susceptibility to injury and general loss of muscle structure, tone, and function. An exciting combination of behavioral interventions have shown that, even in individuals in their seventies, eighties, and nineties, appropriately designed exercise interventions can still cause significant increases in strength and consequent resistance to injuries. Approaches based on biochemistry and endocrinology show that growth hormone, which clearly plays a role in developing young individuals, also plays a very exciting role in the ability to induce a decrease in fat and an increase in lean mass and strength.

[The statement follows:]

STATEMENT OF DR. RICHARD J. HODES

Mr. Chairman, I am pleased to have this opportunity to present an overview of the research programs supported by the National Institute on Aging [NIA]. In the short time that I have served as Director, progress in a number of critical research areas has given me and others in the field a heightened confidence that our research strategies will lead to the prevention or cure of the major diseases and disabilities in older Americans. Examples of these recent advances typify the diversity of NIA's portfolio: new insights into the association of the aberrant amyloid protein with Alzheimer's disease and the discovery of a genetic marker and potential risk factor for this disease; the successful preliminary testing of "trophic factors" to improve muscle strength in the elderly; new analyses revealing declines in the prevalence of 16 major chronic conditions in those above age 65; the use of transgenic technology to explore oxidative damage in animal models with the actual extension of life span; and the use of gene transfer techniques to combat the damaging effects of atherosclerosis in rodents, research that gives real promise for the development of a breakthrough treatment for cardiovascular disease.

As Director, I am challenged to maintain an essential balance between basic and applied research: findings that result from investment in basic research establish the basis for subsequent development in detection, treatment, or prevention interventions. Often, important new clinical interventions are the direct result of support for areas of basic research that were not linked at the time to the disease areas on which they now impact. For example, the "ApoE4" work related to Alzheimer's disease which I will describe for you, would not have been possible without the knowledge gained from previous support by NIH for basic research on ApoE which normally functions as a carrier of blood lipids. Another example of payoff in unforeseen areas was last year's discovery of the specific genetic defect responsible for certain cases of another neurological disease, ALS (otherwise known as Lou Gehrig's disease). This breakthrough was an unexpected and immediate payoff from the research of an NIA grantee, who was researching antioxidant enzymes as related to aging and the nervous system.

Returning to ApoE4 and Alzheimer's disease [AD], NIA-supported researchers recently found that expression of one form of the apolipoprotein E gene, ApoE4, is associated with an increased incidence of AD and could therefore be a major risk factor for AD. It will be necessary to confirm and better understand the association of ApoE4 with AD. Should ApoE4 indeed prove to be a major factor in determining AD susceptibility, modification of ApoE activity would become an attractive target for development of therapeutics. This and many other exciting discoveries are providing insights on how to solve the puzzle of this dread disease which now devastates over 4 million older Americans and their families, with an annual cost of at least \$90 billion.

NIA is supporting cutting edge research on the natural process of aging. One such initiative is focused on the relationships between aging, oxidative damage, antioxidant enzymes, and antioxidant vitamins. Our cells must constantly resist the oxidative damage that occurs as a side effect of normal metabolism. We are keenly interested in discovering the exact mechanisms by which the body, through its own antioxidative enzymes, protects itself from this natural, but damaging, process. There is increasing evidence that certain nutrients, including vitamins C, E, and betacarotene, serve as agents to augment the body's natural protective mechanisms against cellular and subcellular oxidative damage. Preventive effects of antioxidants

may have extraordinary potential to forestall a wide range of diseases such as cancer, ALS, AD, and cardiovascular disease. Additional research is necessary to build more evidence for these associations and to establish the safety for increased intake of these compounds.

Sixty percent of U.S. deaths are due to vascular disease, which has long stimulated NIA's interest in advancing research on age-associated vascular disease. During atherosclerosis (hardening of the arteries), some of the smooth muscle cells which are part of all normal arteries, begin to multiply and produce damaging proteins which are secreted into the walls of the artery. An NIA intramural research team has discovered that these arterial muscle cells, when placed in an environment that simulates arterial injury, proliferate within the artery and invade their surrounding membranes and proteins. The NIA research team is pursuing this line of research with the ultimate goal of developing therapeutic measures to reduce the extent of atherosclerosis, leading to a significant reduction in vascular disease and in health care costs.

Research on aging offers a real opportunity to reduce those many risk factors that lead to the need for costly long term care and the loss of independence among older Americans. One example is osteoporosis—it affects over 25 million Americans, mostly women, and is a serious public health problem since associated fractures are a major cause of disability in older people. Costs associated with hip fractures alone exceed an estimated \$7 billion annually. Recently, NIA has focused attention on treating degenerative conditions such as osteoporosis, osteoarthritis, and muscle atrophy through replacement therapy with “trophic” factors. These factors promote growth and maintenance of tissues such as bone, muscle, and cartilage. In fiscal year 1995, NIA will continue support for these lines of research as well as basic studies to understand and modify age-related changes in bone metabolism and bone cell activity.

Many of the disorders and problems that older Americans face can be best attacked by addressing the behavioral and/or social aspects of the problem. For example, one of our grantees has produced the first nationally-representative database on self-care behaviors practiced by community dwelling older Americans. Many more subjects reported compensating for their particular limitation by making modifications in daily routines, rather than by acquiring and using special equipment or devices or by making changes in their living environment. This and information gained from other NIA-supported research will provide the basis to develop strategies needed to promote the increased use of assistive devices and environmental change to maintain independence and productivity with advancing age. NIA is also pursuing research to develop cognitive and other non-pharmaceutical interventions to maintain and promote independent functioning among older adults who are at-risk for decline in cognitive or perceptual abilities. This work will enable the identification of the most likely methods to reduce both need-for-assistance and injuries.

Many important questions surround the health implications of menopause and hormonal changes in women. NIA will continue support for its ongoing Women's Health and Aging Study which is designed to determine what diseases and other predisposing events cause and influence disability in women age 65 years and older. NIA will also continue funding for newly initiated research on the natural history of menopause and the decline in ovarian function. This initiative will characterize the biological and psychosocial aspects of menopause and its effects on risk factors for age-related disease.

NIA also has a strong commitment to research which focuses on minority populations and the significant differences which exist between them and non-minority populations, such as their relative use of long term care services. Another example of this commitment is the particular initiative NIA developed to specifically recruit African-American and Hispanic populations for dementia studies through its Alzheimer's Disease Research Centers program.

All issues related to aging, including research sponsored by NIA, take on a heightened level of importance in the face of the “graying of America”: those demographic changes that will soon markedly raise the median age of America's population as the baby-boom generation ages. Ultimately, success in reducing morbidity, premature mortality, and the containment of national health care costs will depend upon research to develop the means to prevent, control, or cure those diseases and disorders that produce the greatest need for costly long term care.

Mr. Chairman, the fiscal year 1995 budget request for the National Institute on Aging is \$433,701,000. I will be happy to answer any questions.

BIOGRAPHICAL SKETCH OF DR. RICHARD J. HODES

Date and place of birth: December 31, 1943; New York, New York.

Citizenship: United States.

Marital status: Married, one child.

Education: 1965, B.A., Yale University (summa cum laude), New Haven, Connecticut; 1971, M.D., Harvard Medical School (magna cum laude), Boston, Massachusetts.

Brief chronology of employment: 1968-70, Research Fellow, Department of Tumor Biology, Karolinska Institute, Stockholm, Sweden; 1971-73, Intern and Resident, Department of Medicine, Massachusetts General Hospital, Boston, Massachusetts; 1973-75, Clinical Associate, Immunology Branch, National Cancer Institute [NCI], NIH; 1975-76, Investigator, Immunology Branch, NCI, NIH; 1976-88, Senior Investigator and Chief, Immunotherapy Section, Immunology Branch, NCI, NIH; 1978-79, Clinical Fellow, Medical Oncology, NCI, NIH; 1980-81, Acting Chief, Immunology Branch, NCI, NIH; 1983-88, Deputy Chief, Immunology Branch, NCI, NIH; 1984-85, Acting Chief, Immunology Branch, NCI, NIH; 1988-93, Senior Investigator, Experimental Immunology Branch, NCI, NIH; 1991-93, Chief, Immune Regulation Section, Experimental Immunology Branch, NCI, NIH; and 1993, Director, National Institute on Aging, NIH.

Societies: Diplomat, American Board of Internal Medicine; Board Eligible—Medical Oncology; American Association of Immunologists, 1974 to present; Associate Editor, Journal of Immunology, 1977-79; Program Coordinator, U.S.-Japan Cooperative Cancer Research Program, 1982 to present; Section Editor, Journal of Immunology, 1985-89; Chair, Program Committee, American Association of Immunologists, 1986-88; American Society for Clinical Investigation, 1987 to present; Advisory Editor, The Journal of Experimental Medicine, 1990 to present; Associate Editor, Therapeutic Immunology, 1992 to present; Scientific Advisory Council, Cancer Research Institute, 1992 to present.

Honors and other special scientific recognition: Phi Beta Kappa; Alpha Omega Alpha; Commendation Medal, PHS, 1977; Outstanding Service Medal, PHS, 1988.

ELDERLY ON EXERCISE PROGRAMS

Senator HARKIN. I have seen an example of that in Iowa, a couple of places in Iowa where the elderly are on exercise programs, and what has happened to them.

Dr. HODES. Quite extraordinary.

Senator HARKIN. Extraordinary.

Dr. HODES. We would like to have an opportunity to refine those observations and design interventions which are most effective and safe in an older population. It ultimately will lead to greater independence and less dependence on long-term care and hospitalization and preserve the quality as well as the extent of life.

BEHAVIORAL RESEARCH

I would finish by noting that behavioral variables are important in the spectrum of research carried out by the Institute. These include demographic population studies, such as the health and retirement survey, which are pointing out the interactions of health status, disease, retirement decisions, and work force participation in an important way for future planning.

I would also emphasize that an exciting direction, alluded to by Dr. Grady as well, for behavioral research is its convergence with neurobiology. In the area of cognition and cognitive psychology, we have seen an exciting ability to correlate behaviors, cognition, and learning with events that can be visualized by imaging techniques in the brain.

The distance between behavioral science and basic biological science is rapidly disappearing and creates exciting opportunities.

I do not have to more than echo in generic terms the strain, with this increased program, that the personnel restrictions on administrative and intramural programs are causing. I would be happy to submit that in greater detail for you.

[The information follows:]

PERSONNEL REDUCTIONS

Current research advances suggest possible approaches for reducing age-associated diseases and disabilities. These include clinical studies to transfer basic research to clinical practice. Reductions in FTE's specifically impair the recruitment into the intramural research program of experienced, highly qualified investigators who have clinical qualifications to conduct these studies.

The fiscal year 1994 House and Senate Appropriations Committee reports conveyed expectations that NIA expand its intramural research initiative on cardiovascular disease by establishing a laboratory for vascular studies. The best NIA could do to honor Congressional intent was maintain its intramural cardiovascular initiative at approximately the fiscal year 1993 dollar level (other intramural initiatives, out of necessity, were reduced). This initiative has the ultimate goal of developing therapeutic measures to reduce the extent of atherosclerosis and cardiovascular disease, leading to a significant reduction in vascular disease and in health care costs.

The FTE reductions have and will continue to impact NIA's research management and support activity, which supports those scientists who must maintain proper stewardship and scientific oversight of the \$350 million in grants and contracts awarded each year by the NIA. Decreased staffing levels are translating into a lessening ability to steer research efforts into promising new avenues to develop interventions that will decrease the impact of disease and disability and the need for costly long term care.

Senator HARKIN. You do Alzheimer's research, along with how many other Institutes?

Dr. GRADY. We do.

[A show of hands.]

Dr. VARMUS. Pat Grady, Mental Health, Nursing.

Senator HARKIN. What percentage of your research goes toward Alzheimer's? What percentage of your total research?

Dr. HODES. It is slightly over 50 percent. That reflects both professional judgment and our efforts to act consistently with the expressed desire of Congress in past years as well.

Dr. VARMUS. Now, with the involvement of ApoE, where the Heart Institute was an investor in the beginning, it suddenly becomes a major player.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

BEHAVIORAL RESEARCH

Question. Your Institute supports a broad range of aging-related research including projects that focus on the behavioral or social aspects of aging. Can you describe some recent research findings from your behavioral and social research portfolio, and how this research is critical to the overall mission of your Institute?

Answer. Medical research acknowledges that scientific advances in disease prevention, detection, and treatment must be linked with understanding of social and behavioral influences on the health of individuals. For older people, new findings

specify the social and behavioral factors that maintain health and functioning, identify interventions for improving quality of life, and project trends in the social, economic, and demographic characteristics of the aging population.

In the area of health maintenance, research focuses on self-care—what older people do to maintain their own health. Data from the first nationally-representative study on self-care behaviors practiced by Americans ages 65+ indicate that most do practice some form of self-care to compensate for functional limitations associated with chronic health care problems. However, the amount and type of self-care varies by age, disability and living arrangement, and self-care practices and the receipt of informal assistance supplement each other.

Behavioral and social factors are often key to differences between the majority population of older people and special groups of elders. For example, studies of the use of formal, long term care services by minority elders shows half the utilization compared with their non-minority counterparts. While the reasons for this disparity are complex, current research suggests a combination of barriers to care and minority willingness to maintain impaired older people in the family and community. Among the oldest old, NIA-supported research shows that urban, impoverished minority individuals and non-minority elderly have similar reliance on formal care and elder services. However, the social network of minority older people is more extended, involving a wider range of family, community, and church affiliations, than among non-minorities. Recent studies focused on rural elderly found that 61 percent of rural residents, compared with 40 percent of urban respondents, expressed a need for formal services that were not available. These studies, based on analysis of factors that are based in social and behavioral differences, point to the need to look at the social context of aging in addressing physical, emotional, and health issues in later life.

Recent research is also focusing on the determinants of nursing home use, new forms of nursing home care, and innovative strategies for improving long-term care. Preliminary findings about dementia special care units, a new form of nursing home services, indicate that while many provide extra care, some call themselves "special" without providing extra staffing, programs, or environmental modifications. Research also demonstrates the benefit of behavioral strategies for improving the quality of care for nursing home residents. The NIA intramural research program has a long standing interest in behavioral interventions to treat or prevent age-associated diseases and disabilities. The NIA and the National Institute for Nursing Research have been collaborating to develop practical procedures adaptable to the nursing home setting to reduce incontinence and protect against hip fractures. Behavioral techniques in this area represent one of the most powerful approaches to treat and prevent such disabilities, preserve health and reduce health care costs.

Behavioral research on cognition and aging helps us understand how older people carry out everyday tasks that range from performance at work to taking medications. While mental slowing with age is one of the most consistent findings in cognitive research, no agreement exists on the causes of such changes in later life. Research suggests that cognitive changes with age are mediated by a variety of "control influences": strategies that people adopt to control their performance, beliefs they have about their own abilities, and prior knowledge about the task they must perform. These control influences can either compensate for or exacerbate problems from cognitive decline.

Projections of life expectancy and disability among the very old can have enormous implications for the Social Security and Medicare trust funds in terms of their long-term forecasts of the size and health of the older population. Research shows that the mortality trajectory at extreme old ages may not follow an exponentially increasing curve, but may level off or even decline. This implies that the oldest-old population will grow far more than either Census or Social Security projections indicate. Complementing these projections are medical demographic findings which suggest a significant decline in the prevalence and incidence of chronic disability for the older population, especially among the very old.

The first wave of the Health and Retirement Study (HRS) is now being analyzed. The HRS will provide data for retirement policy decisions and the monitoring of the impact of Health Care Reform and the Americans with Disabilities Act. Preliminary findings suggest that labor force participation at older ages is determined by both health status and the structure of private pensions. Further, there appears to be a gap between retirement behavior and retirement preferences; while the majority of respondents prefer to stage their retirement, most actually move from full-time to zero hours with no transition. Additionally, one third of respondents experience "job lock" because they fear losing either pension or health insurance benefits if they were to change jobs.

ALZHEIMER'S DISEASE

Question. Several weeks ago, I had an opportunity to meet with Dr. Allen Roses of Duke University. He has been conducting some exciting new research that could lead to a way to diagnose Alzheimer's disease. Would you give us a status report on that research? Is this research being funded by NIA?

Answer. ApoE4, a variant of a blood protein whose gene is located on chromosome 19, has been shown by Dr. Roses and others to be associated with an increased risk of Alzheimer's disease [AD]. The association of ApoE4 with increased risk of AD is dramatic in members of some families in which late-onset AD is inherited. However, in the general population the association is not quite as clearcut. Individuals with the ApoE4 gene appear to be at somewhat increased risk for AD. A large proportion of AD patients do not carry the ApoE4 gene, and there are many octogenarians with the ApoE4 gene who do not suffer from AD. For this reason, ApoE typing should not be interpreted as diagnostic, but the usefulness of identification of the first AD susceptibility gene for late onset AD cannot be overemphasized. Scientists can now begin to discriminate between the effects of ApoE in the epidemiology of AD and other, possibly environmental, causes. Researchers may be better able to explain the biochemical pathways that result in AD by determining the role of ApoE4 in AD pathogenesis. Perhaps when more is known about its role in AD, ApoE typing may have some diagnostic utility in conjunction with other, as yet unidentified, risk factors.

Research on the role of ApoE in AD has accelerated tremendously in the last year. The NIA has funded the studies by Dr. Roses and colleagues through the Alzheimer's Disease Research Center grant at Duke University. Dr. Roses' research has also been supported by his Leadership and Excellence in Alzheimer's Disease award, a seven-year grant from the NIA. The NIA supports major projects on the pathobiology and epidemiology of ApoE in AD in several other laboratories as well. Numerous new applications for grants in this area of research are presently under review.

Question. Over the past few years, this Subcommittee has supported a network of centers conducting research on Alzheimer's. Much of the progress that has been made in the understanding and treating of this disease has come from those centers. Under the circumstances, I was troubled to learn that the centers will be level-funded (\$34 million) under your fiscal year 1995 budget. What is the rationale behind this decision?

Answer. The Alzheimer's Centers program began in 1984 with the funding of five Centers. From 1985 until 1991, 23 additional centers were added bringing the total to 28. In addition, 27 Satellite Diagnostic and Treatment Clinics were added in 1990-92 to serve minority and other under-represented patient groups. Since 1992 no additional units have been added. The major growth phase is over and we are now in a consolidation phase as the centers mature. Therefore, the budget has risen only slightly in the past several years.

The centers provide the infrastructure for research by providing access to patients and pathological brain material for researchers to study. Originally funding for research projects was included in the centers because there was not as large a research community as there is now. Over the years, more scientists outside of the centers have been funded independently but still draw upon core resources provided by the centers. It is now no longer as necessary to fund research directly in all of the centers, but the continued support of core activities is critical. We anticipate that in the future, some of the centers will become core facilities to serve as a resource to encourage scientists to apply for support for independently funded Alzheimer research projects. With the gradual transition of research to independently funded grants, there is less need to increase the center budgets substantially.

Question. In last year's report, we encouraged the development of a long range plan to slow the progression of Alzheimer's. Would you report on the status of that plan?

Answer. The long-range plan to slow the progression of Alzheimer's disease is being implemented through the development of a series of research planning workshops to identify future directions for research. The primary focus of the first workshop, to be held on May 24-26, 1994, is the development of a plan directed toward accelerating the discovery of treatments for AD. The views of approximately 40 scientists from around the world will be solicited with respect to scientific opportunities, resource needs, and impediments to the progress of research in this area. The workshop will address a comprehensive range of scientific issues in order to identify critical targets for interventions and will develop a consensus regarding the most effective mechanisms for altering the progression of the degenerative course of the disease. The results of the workshop will be shared with the scientific community

through publication of the participants' concept papers and of overviews of the discussions in a scientific journal. These recommendations will form the basis for future scientific initiatives in Alzheimer's disease research. The document will also be forwarded to Congress to inform the members about the opportunities we will pursue to first understand and then stop this disease.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND
SKIN DISEASES

STATEMENT OF LAWRENCE E. SHULMAN, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Shulman, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Dr. SHULMAN. Thank you for pronouncing it so well. This name of ours, Musculoskeletal, has always been a problem for us. I say this, Mr. Chairman, because you once told me that we should change the name of our Institute because it was so hard to pronounce.

Senator HARKIN. Very hard. I had a little practice, though.

RESEARCH OPPORTUNITIES

Dr. SHULMAN. Mr. Chairman, if we had a 50-percent increase in our budget, our gratitude would be boundless. [Laughter.]

Senator HARKIN. About as succinct as I have ever heard it.

Dr. SHULMAN. I would first like to echo the sentiments of Dr. Alexander that a 50-percent increase would energize all of our investigators. It would be absolutely superb.

As for what we would do if you did succeed in getting us this 50-percent increase, we would raise our success rate, which is under 20 percent now, to about 40 percent. We would develop a whole series of initiatives in basic and clinical science.

This has been an extraordinarily productive year for the investigators working with NIAMS support. Some of the successes are cataloged in our opening statement that you have. We want to do a great deal to build up and develop the area of basic connective tissue research for which our Institute has primary responsibility. As you know, this includes research on the three largest organs of the body: The muscles, the bones, and the skin. Without them we could not move; we would literally fall apart.

Seriously, we do have broad responsibilities and a very large research agenda; and we as a consequence have numerous scientific opportunities. I will just touch upon a couple of these because of the timeframe.

OSTEOPOROSIS

The first area I would like to discuss is osteoporosis. In January it was announced for the first time that a gene for osteoporosis had been discovered. This was a fantastic achievement. This has been a very colorful hearing, but I want to add a little more color to it by showing you the red cover of the journal; *Nature*; from January, in which this discovery made by Australian scientists, was reported.

The scientists have discovered the gene that predicts the density of bones. The density of our bones, as we all know, is the determinant of whether or not they will fracture as a result of osteoporosis, and contributes to the problem of frailty.

This gene which was recently discovered is actually the gene for the receptor for vitamin D. We knew that vitamin D is important for the way that we absorb and eliminate calcium, but we now know also that vitamin D is very important for bone turnover itself.

The implication is that if this gene can predict bone density, we can identify in early life those who will be susceptible and those who will not be susceptible to osteoporosis and bone fractures later on. For those who are susceptible, we can intensify efforts, such as encouraging extra intake of calcium, enough exercise, and enough vitamin D itself so that our young people can build the most bone mass possible.

PREPARED STATEMENT

And speaking of calcium, during the past year there have been several articles indicating that we should all be taking in much more calcium. We have the results of childhood studies in twins that indicate that there is not enough calcium intake. We also have studies on the elderly in France indicating that if you give extra calcium and vitamin D to women in nursing homes they suffer fewer fractures than those who do not receive the supplements.

As a follow-up to these and other discoveries, we are organizing a consensus development conference on optimal calcium intake, to take place this June.

Senator HARKIN. Here in Washington?

Dr. SHULMAN. Yes, sir.

[The statement follows:]

STATEMENT OF DR. LAWRENCE E. SHULMAN

Mr. Chairman, members of the committee, it is a great privilege and pleasure to appear before you once again to discuss the many research programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIAMS], and to highlight some of our research accomplishments this past year.

NIAMS has a large, complex research agenda. It encompasses a broad array of diseases that affect the very components of the body that shape our form and structure, and enable us to move. All together, these diseases of the joints, muscles, bones, connective tissue, and skin will afflict nearly every American at some point in their lifetime. Moreover, these diseases affect people of all ages, race, and color. Some of these disproportionately affect special populations, such as women, minorities, children, or the elderly. The NIAMS is dedicated to lessening the burden imposed by these diseases. I am pleased to report to you that we have seen promising advances in several areas.

Osteoporosis is an eminently preventable disease that results from porous bone that easily fractures. At least 25 million American women suffer from osteoporosis. It is the major underlying cause of bone fractures in both postmenopausal women and the elderly. Researchers have recently found a gene that can predict bone density. This landmark discovery will make it possible to identify, early in life, individuals at high risk for osteoporosis and to initiate prevention programs. One way to build bone—and thus prevent osteoporosis—is to take in enough calcium. With this in mind, the NIAMS is sponsoring a Consensus Development Conference this year to establish guidelines for optimum levels of calcium intake for people of different ages.

Another high priority for our Institute is research on the many forms of arthritis. We are making much progress in this field, including research on diseases such as lupus, rheumatoid arthritis, scleroderma, and fibromyalgia that largely affect

women. Recent research has uncovered clues to explain why rheumatoid arthritis, a major crippling disease, improves greatly in three-fourths of patients during pregnancy. The discovery indicates that genetic differences between mother and child promote immune reactions that combat the arthritis. These findings offer a new avenue of research into the mechanisms of remission in rheumatoid arthritis, and thus, may lead to new treatment strategies.

There has been much discussion, over the years, on the possible benefit of the antibiotic minocycline in treating rheumatoid arthritis. The NIAMS has recently completed a large multicenter clinical study on minocycline in rheumatoid arthritis; it found that this agent has some benefit and low toxicity in treating the arthritis. Because it remains unclear how minocycline works, NIAMS is convening a group of scientists to explore the results of the trial.

I would like to share with you now the progress we are making with lupus, a serious disease that disproportionately affects women, especially African-American women. In recent initiatives, the NIAMS is now supporting new basic research on the molecular causes of lupus, and basic and clinical research on why lupus is more prevalent in certain populations. In one of the exciting new advances in lupus research, scientists have just discovered that replacing a single defective gene can prevent lupus tissue injury and reduce autoantibodies in a mouse model of lupus. This gene, called the fas gene, normally enables the body to eliminate damaged or harmful cells, such as those that cause tissue damage in lupus. In the mouse model, researchers replaced the flawed gene, and the mice no longer developed signs of lupus. This remarkable research may open the door to new treatments for women with lupus.

To increase research on arthritis in children, the NIAMS organized a highly productive scientific workshop this year. This workshop covered basic and clinical research for several rheumatic diseases of children. Based on the published proceedings, the Institute will actively encourage new research in areas recommended by the leaders in this field. Also this year, the NIAMS funded an Exploratory Research Center in Juvenile Rheumatic Diseases where investigators will study the genetics and other aspects of these diseases.

A very important breakthrough occurred this year in research on the causes of spinal arthritis. You may recall that three years ago I reported to you a remarkable discovery in which a human gene, HLA-B27, that is found in over 90 percent of patients with spinal arthritis, was injected into rats. These transgenic rats developed not only arthritis of the spine and joints, but also skin and nail lesions of psoriasis and Reiter's disease, both associated with spinal arthritis. This research indicated that genetics plays an essential role in causing these diseases. The same study has now been repeated using HLA-B27 transgenic rats that have been bred in a completely germ-free environment. Remarkably, although the germ-free rats still developed the skin and nail changes, they did not develop the arthritis that was observed in animals raised in a normal environment. This research proves that the HLA-B27 gene alone cannot induce the arthritis—an infectious agent must also be present. The challenges now are to identify the responsible infectious agent and to find the link between it and the gene.

Another important new advance this year is a new highly sensitive test, using modern techniques of the polymerase chain reaction, to detect Lyme disease bacteria in the joint fluids of patients with arthritis caused by Lyme disease. This test will greatly aid in the diagnosis and treatment of Lyme arthritis by making it possible to accurately determine when bacteria is the cause of the chronic arthritis, and when it is not.

Osteoarthritis is the most common form of arthritis, affecting an estimated 16 million Americans. In a recent study in an animal model of osteoarthritis, scientists have shown that the antibiotic doxycycline prevented the development of the arthritis because of the ability of doxycycline to block collagenase, an enzyme that degrades cartilage. To encourage more research on this common and disabling disease, NIAMS is sponsoring a workshop on "New Horizons in Osteoarthritis," and a Consensus Development Conference on Total Joint Replacement.

NIAMS continues to support research on both inherited and acquired connective tissue diseases, such as osteogenesis imperfecta, Marfan syndrome, Ehlers-Danlos syndrome, and scleroderma, and will hold a workshop in the fall to build on recent scientific advances. Recent discoveries in osteogenesis imperfecta—or "brittle bone disease"—include a new mouse model of the disease. Scientists have also discovered that the weakness of bone in this disease is due more to abnormal crystallization of bone than to defective collagen production.

Research on all diseases of bone is important to the NIAMS. To facilitate and enhance knowledge and understanding of bone diseases, the Institute will award a

grant to establish an Information Resource Center on Osteoporosis, Paget's Disease, and Related Bone Disorders.

Basic research is critical to the mission of the NIAMS. One of the Institute's greatest advances this year occurred in fundamental muscle research when scientists discovered the 3-dimensional structure of the main protein of muscle. This exciting discovery reveals with precision how the molecules in muscle use chemical energy to produce force and motion.

Much progress has also been made in the last several years in research on the genetic causes of inherited skin diseases, such as epidermolysis bullosa. Exciting advances at the molecular level are providing insights into the underlying causes of many of these skin diseases.

This year, the NIAMS issued a request for applications to establish research registries for rare diseases, including skin diseases such as the ichthyoses. The Institute will also support two additional Research Core Centers for Skin Diseases to reach its goal of six centers.

As a followup to a previous workshop, NIAMS will sponsor a scientific workshop on alopecia areata to provide for further exchange of information and to stimulate more research on the disease.

We continue to be extremely proud of the research being conducted in our Intramural Program. Scientists are making exceptional progress in research on the inherited rheumatic disease, familial Mediterranean fever (FMF). They have localized the genetic defect for FMF to the short arm of chromosome 16, and they are now collaborating with investigators at the National Center for Human Genome Research to focus in on the specific gene. Two new enzyme deficiencies causing muscle-weakening disease have been discovered. The genetics of immune-mediated inflammation is being actively investigated.

As you can see, Mr. Chairman, the programs of the NIAMS are many, and research opportunities abound. To continue our research efforts, we are requesting a fiscal year 1995 budget for the NIAMS of \$228,413,000. I will be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. LAWRENCE E. SHULMAN

Born: July 25, 1919, Boston, Massachusetts.

Education: Harvard University, A.B., 1941; Yale University Graduate School, Ph.D., 1945; Yale University School of Medicine, M.D., 1949.

Professional history: 1949-50, Intern, Medicine, The Johns Hopkins Hospital, Baltimore, Maryland; 1950-51, Ayerst, McKenna and Harrison Fellow in Endocrinology, The Johns Hopkins University School of Medicine; 1951-52, Vernon D. Lynch Fellow in Internal Medicine, The Johns Hopkins University School of Medicine; 1952-53, Assistant Resident, The Johns Hopkins Hospital; 1954-present, Physician, The Johns Hopkins Hospital; 1955-75, Director, Connective Tissue Division, Department of Medicine, The Johns Hopkins University School of Medicine; 1960-66, Physician-in-Charge, Arthritis Clinic, The Johns Hopkins Hospital; 1966-67, Physician-in-Charge, Connective Tissue Clinic, The Johns Hopkins Hospital; 1966-69, Physician-in-Chief, Division of Chronic and Community Medicine, The Baltimore City Hospitals, Baltimore, Maryland; 1970-73, Associate Professor of Medical Care and Hospitals, The Johns Hopkins University School of Hygiene and Public Health; 1964-present, Associate Professor of Medicine, The Johns Hopkins University School of Medicine; 1976-80, Acting Associate Director for Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Metabolism, and Digestive Diseases; 1980-83, Associate Director, Arthritis, Musculoskeletal and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; 1983-86, Director, Division of Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; 1986, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases; 1987-present, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Professional organizations: American Association for the Advancement of Science, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association (President, 1974-75), American Society for Bone and Mineral Research, The Arthritis Foundation, Brazilian Society of Rheumatology, Carla Curzio Neapolitan Society, Lupus Foundation of America, New York Academy of Science, Pan American League Against Rheumatism (President, 1982-86), Society for Clinical Trials, Sydenham Society, Society for Investigative Dermatology.

SYSTEMIC LUPUS ERYTHEMATOSUS

Senator HARKIN. A second area I would like to discuss is lupus, a serious disease of young women, especially African-American women. We now have excellent genetic mouse models of lupus. Appearing in this week's issue of the Proceedings of the National Academy of Sciences is the news that investigators in Alabama, supported by NIAMS, have discovered a gene that is defective in lupus, thus causing autoimmunity.

In other words, in this mouse model the gene which controls the death of cells is defective. If you replace the defective gene with a normal gene, you can prevent this mouse model from developing kidney disease and the damaging autoantibodies associated with lupus. This is just one example of the exciting discoveries upon which we will continue to build and develop.

My overall response to your question is twofold. First is that there is so much to be accomplished and we can well utilize increased support; we all have plans, specific plans, which we can immediately implement.

The second issue is that there are so many disorders that really have not received enough scientific attention but need to be addressed. Let us take a disease such as scleroderma, a terrible disease of women. It is a serious, disabling, potentially lethal disease. We need to do more research in this and we just have not been able to do it.

FTE SITUATION

Finally, I would like to address the FTE situation. I am speaking now for the younger Institutes. I, along with my colleagues in the newer Institutes, face severe FTE constraints. Dr. Alexander, the Director of NICHD and its new National Center for Medical Rehabilitation Research, a new Institute is also in trouble with respect to the FTE situation. We new Institutes are small and thinly staffed. If we are forced to sustain more FTE cuts it will be destructive, not only to our intramural program, where we have taken the previous cuts, but also to our extramural programs and the scientific management of the Institute.

Thank you very much for this opportunity.

Senator HARKIN. Thank you, Dr. Shulman.

I am sorry, my time planning is very bad. I have got nine to go and I should have been done by now. I will just go another 15 minutes. I just ask you to please take that into account.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RHEUMATOID ARTHRITIS

Question. The clinical trial on the effectiveness of minocycline in the treatment of rheumatoid arthritis was to end this past year. Can you report on the results of that trial?

Answer. The Minocycline in Rheumatoid Arthritis [MIRA] clinical trial, which was conducted at six clinical centers across the United States, ended in 1993. The two main objectives of the study were: (1) to determine whether minocycline produces "meaningful improvement," defined as a net 50 percent reduction in the number of tender and swollen joints, in patients with rheumatoid arthritis; and (2) to determine whether long-term treatment with minocycline causes adverse side effects in patients with rheumatoid arthritis.

The results of the MIRA clinical trial, which were reported at the November 7, 1993, Annual Scientific Meeting of the American College of Rheumatology, show that minocycline has some benefit for treating rheumatoid arthritis; how effective minocycline is compared to other treatments for rheumatoid arthritis remains to be determined. On March 9, 1994, NIAMS convened a scientific workshop to review the results of the MIRA trial and to discuss what further avenues of basic and clinical research are appropriate given these results. Additional analyses of the data from the trial were presented along with a number of promising research recommendations. NIAMS will work with the scientific community to further basic and clinical research on the efficacy and actions of antibiotics in rheumatoid arthritis.

Question. The Committee has also encouraged NIAMS to explore whether rheumatoid arthritis can be relieved or cured through the intravenous administration of antibiotics.

Can you report on the Institute's plans to respond to the Committee's directive?

Answer. As requested by the Senate, NIAMS will initiate a pilot clinical trial to study the efficacy of intravenous antibiotic therapy in treating rheumatoid arthritis. A Request for Applications [RFA] was issued on February 25, 1994. NIAMS anticipates funding one award for a total cost of up to \$500,000.

OSTEOPOROSIS

Question. Osteoporosis affects more than 26 million Americans, 20 million of whom are women, and costs the Nation over \$10 billion each year.

Can you update us on research progress in this area? And please describe NIAMS' level of funding for osteoporosis research?

Answer. There has been tremendous progress this year in osteoporosis research with the discovery of a gene that could facilitate early identification of individuals at risk for osteoporosis. The gene codes for the vitamin D receptor and its metabolites which influence many processes associated with bone, including bone turnover and the absorption and excretion of calcium. Osteoporosis usually results from the deficient attainment of peak bone mass in early life and/or excessive rates of bone loss in later life. Heredity has long been suspected of influencing bone density, but there has been little direct evidence for this until now. This new discovery calls for more research on the genetic regulation of bone turnover, the vitamin D receptor, and the actions of vitamin D and its metabolites on bone. These investigations could lead to new targeted approaches to preventing osteoporosis.

In other research on osteoporosis, scientists have discovered a new animal model in which the bones of genetically engineered (transgenic) mice bear a striking similarity to the bones of people with osteoporosis. The transgenic mice bearing the gene for interleukin-4 show a marked decrease in bone mass and have bones that are significantly more fragile than the bones of normal mice. This new model will be especially helpful in studying basic mechanisms in osteoporosis.

NIAMS has launched several new initiatives in osteoporosis, including plans to: (1) encourage and effect more research collaboration among both NIH and other Federal agencies, through the establishment of a Federal Working Group on Bone Disorders, (2) further public information and education on bone diseases, by awarding a grant for establishment of a Resource Center on Osteoporosis, Paget's Disease and Related Bone Disorders, and (3) sponsor a Consensus Development Conference on the influence of calcium on osteoporosis with the goal of establishing optimum levels of calcium intake for individuals of all ages.

Funding for osteoporosis in fiscal year 1993 was \$42,148,000 and is estimated to reach \$46,174,000 in fiscal year 1994 and \$48,077,000 in fiscal year 1995.

CHILDHOOD MUSCULOSKELETAL DISEASES

Question. It is my understanding that the causes of most childhood musculoskeletal diseases remain unknown.

Can you describe the major areas of research NIAMS is currently sponsoring in the field of childhood musculoskeletal diseases.

Answer. In September 1993, the NIAMS held a highly productive scientific workshop on basic and clinical research for the several rheumatic diseases of children. Following publication of the workshop proceedings, NIAMS will issue a Request for Applications [RFA] to stimulate both basic and applied research on rheumatic diseases in children as recommended by leaders in the field.

Currently, the Institute is supporting research to study genetic factors, causal mechanisms, pathogenesis, and treatment of some juvenile rheumatic diseases. In one study, researchers are investigating the genetic susceptibility and autoimmune processes in juvenile dermatomyositis, a systemic disorder characterized by inflammation of the skin, tissue, and muscles. Researchers in one of the Institute's centers are also conducting a study of the genetic factors of juvenile dermatomyositis to determine possible alternatives to immunosuppressive therapy.

NIAMS has also funded in fiscal year 1993 a Juvenile Rheumatic Diseases Research Center to support the expansion of multidisciplinary research on the causes of juvenile arthritis and the development of new treatment strategies. Scientists at this center will investigate the genetic basis, causes of inflammation, and the role of bacteria and viruses as triggers of these diseases.

The Institute funds research on other childhood musculoskeletal diseases as well, including osteogenesis imperfecta or "brittle bone disease," muscular dystrophy, Ehlers-Danlos syndrome, Marfan syndrome, and scoliosis. In research on osteogenesis imperfecta, recent advances include a new mouse model of the disease. Researchers have also discovered that the weakness of bone in this disease is due more to abnormal crystallization of bone than to defective collagen production.

In recent research on muscular dystrophy, researchers have discovered a gene therapy technique that prevents mice from developing a condition similar to Duchenne muscular dystrophy [DMD], the most common form of childhood muscular dystrophy. By inserting a normal gene for the protein dystrophin into mice that lacked a functioning form of the gene, researchers were able to correct the defect that causes the muscle degeneration associated with muscular dystrophy.

NIAMS is also concerned with musculoskeletal injuries that occur in children who are active in sports. In this area, the Institute has issued a program announcement [PA] to sponsor research to understand the nature and risk factors for sports injuries in youth and to seek preventive measures to reduce the occurrence of sports injuries.

OSTEOARTHRITIS

Question. An estimated 16 million Americans suffer from osteoarthritis, the most common of all the rheumatic diseases. In its fiscal year 1994 Report, the Senate Committee asked NIAMS to place special emphasis on research on this degenerative joint disease.

Please update us on your plans in this area.

Answer. First let me report to you one of the exciting new research advances on osteoarthritis. In a recent study of osteoarthritis, investigators have determined that the antibiotic doxycycline may be useful in the treatment of this disease. In an animal model of osteoarthritis, it was shown that doxycycline was able to block or greatly reduce the onset of osteoarthritis because of its ability to inhibit the formation of collagenase, an enzyme that degrades collagen, a major component of joint cartilage.

The NIAMS is supporting some exciting initiatives in osteoarthritis. In April 1994, NIAMS will sponsor an Osteoarthritis Research Workshop entitled, "New Horizons in Osteoarthritis," designed to provide a forum to increase the exchange of scientific ideas and to establish directions for future research. Following the workshop, the Institute will issue a Request for Applications [RFA] to invite more basic and clinical research projects devoted to osteoarthritis.

JOINT REPLACEMENT

Question. It is my understanding that joint-replacement surgery has yielded excellent results in the quality of life for individuals whose joints are damaged by diseases such as osteoarthritis.

What steps has your institute taken, if any, to design better implants of improved materials and achieve lasting fixation of the joint replacements?

Answer. Orthopaedic joint implants are very commonly used in the treatment of musculoskeletal diseases and injuries. In 1992, there were an estimated 400,000 joint replacements performed on knees or hips. It is estimated that approximately 5,000,000 people in the U.S. currently have an orthopaedic device implanted. These orthopaedic devices have had great general success in reducing the morbidity and disability that may result from musculoskeletal diseases. To further research in this area, in October 1993, NIAMS issued an RFA inviting Interactive Research Grant Applications on new orthopaedic biomaterials for the development of improved and longer lasting orthopaedic devices. We intend to make an award in the fall of 1994. Also, NIAMS, in collaboration with the NIH Office of Medical Research Applications, will hold in the fall of 1994 a Consensus Development Conference on Total Joint Replacement.

QUESTION SUBMITTED BY SENATOR HATFIELD

FIBROMYALGIA

Question. Dr. Shulman, last year the Subcommittee expressed its interest in research into the causes of fibromyalgia. Would you please update the Subcommittee on the status of research in this area?

Answer. I am pleased to report to you that the Institute issued a Request for Applications [RFA] inviting applications for basic research on the pathogenesis of fibromyalgia. The RFA is intended to promote research that will improve our understanding of the basic causes and mechanisms of fibromyalgia. It will also identify critical processes and mediators of disease that could be used to establish a rational basis for new and effective treatments. To date, we have received 18 applications in response to the RFA. The Institute expects to support 5 to 7 new research grants, with an anticipated award date of September 30, 1994.

In addition, in May 1993, the NIAMS held a scientific workshop on the current status and future directions of fibromyalgia research, the proceedings of which will be published in the *Journal of Musculoskeletal Pain*.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION
DISORDERS

STATEMENT OF JAMES B. SNOW, JR., M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Snow, Director of the National Institute on Deafness and Other Communication Disorders.

Dr. SNOW. Thank you, Senator Harkin.

If we had a 50-percent increase, we would utilize it to strengthen our investigator-initiated research portfolio. We would go to a 50-percent success rate. It is from that portfolio that the exciting breakthroughs in sensory cell regeneration have occurred. We now have evidence that it occurs in humans as well as other mammals.

We have evidence that functional connections develop with these hair cells; they really work; and there is evidence that the factors, the molecular factors, that produce this regeneration, are present in the ear itself.

We have labeling studies that now show that sensory cell regeneration happens in vivo, that is, in the intact animal and in humans as well as in culture. So a very intense search is underway for the molecular events that initiate regeneration. We need to find the growth factors and the other factors that are responsible for initiating this process.

You are aware of our successful national multipurpose research and training centers program. We have these in the areas of hearing, balance, voice, speech, and language. You are perhaps familiar with the one at the University of Iowa, the National Center for Voice and Speech, directed by Dr. Ingo Titze. We need to expand these in the areas in which they already exist and we need to develop them in other areas of the NIDCD's responsibility.

In the area of training and career development, we would increase the number of career awards by 25 percent. We would increase the number of full-time training positions by 80 positions, compared to 185 that we have in this year's appropriation. We would accelerate the contracts supporting the clinical trials for hearing aid research and development, and we would take advantage of the opportunities for language intervention in high-risk children and the development of epidemiologic information in low birth weight infants.

PREPARED STATEMENT

We need to develop our intramural program. The FTE ceiling, as Dr. Shulman mentioned, is a real hardship for a new Institute. We had to slow and literally stop the development of our intramural program. It is only through that program that we are likely to make the most rapid progress in the molecular genetics of heredi-

tary hearing impairment and in the development of vaccines against otitis media.

I will pause for the sake of others.

[The statement follows:]

STATEMENT OF DR. JAMES B. SNOW, JR.

It is a pleasure to appear before this committee to discuss the programs and progress of the National Institute on Deafness and Other Communication Disorders [NIDCD]. The NIDCD supports research that will benefit the 46 million Americans challenged by communication disorders and provide basic new knowledge about the normal processes of human communication.

Five years ago, when the NIDCD was just beginning to support research as a new institute, only a few genes causing deafness had been found and those were genes discovered in diseases in which deafness was only a part of the problem. Now, more than twenty genes for hereditary hearing impairment have been found. Some of these cause syndromes which include identifying features in addition to deafness. Nonsyndromic hearing impairment, on the other hand, is the most prevalent form of hereditary hearing impairment throughout the world, and now several nonsyndromic deafness genes have been found. Among these are an autosomal dominant gene found by NIDCD funded extramural scientists, a mitochondrial gene found by an extramural team, and an X-linked, dominant gene found by NIDCD intramural scientists. The X chromosome gene is near the gene responsible for Duchenne muscular dystrophy [DMD]. NIDCD intramural scientists are trying to determine if the DMD gene product, dystrophin, is expressed in the inner ear. The next step in the study of hereditary hearing impairment will be to determine the structural and functional roles of the genes expressed throughout the auditory system.

For several decades, there has been great concern about the need to improve hearing aid technology, especially to develop aids that would permit the understanding of conversation in noisy environments. The NIDCD and the Department of Veterans Affairs have developed a five-part collaboration designed to yield a comprehensive approach to this long-standing problem as well as address many other hearing aid issues and to offer tangible help to the 20 million Americans who could benefit from improved hearing aids. These initiatives encourage basic research on the effects of signal processing and ways to measure the benefit of amplification for hearing-impaired persons and the development of a program for design and evaluation of new and existing strategies and technologies. Much needed clinical trials are scheduled to begin in fiscal year 1995. Also we will hold the first biennial interdisciplinary forum on hearing aid research and development in 1995. By identifying the appropriate resources, forging strong collaborations, and fostering innovation, we believe these initiatives demonstrate a responsible and cost-efficient way to apply basic and clinical research to a major problem.

Progress in other areas has created outstanding opportunities for further research. Clinical application of molecular and cellular biology to the problem of the loss of auditory and vestibular hair cells caused by commonly administered, lifesaving antibiotics has yielded a strategy to minimize or prevent ototoxicity.

The NIDCD places a high priority on the development of vaccines against otitis media. Intramural scientists are collaborating with scientists at the National Institute of Child Health and Human Development, NIH, and the Center for Biologics Evaluation and Research, FDA, to identify suitable antigen (foreign protein) candidates for conjugate vaccines.

Glutamate is the major excitatory neurotransmitter in the mammalian brain, and an extensive family of receptors mediate its actions. Evidence links glutamate receptors to a range of neuronal functions including synaptic development and plasticity, learning, and memory. Ironically, glutamate and glutamate agonists are neurotoxins and can result in neuronal degeneration and death. Glutamate receptors may be involved in disorders such as stroke, epilepsy and some neurodegenerative diseases. Glutamate receptors have been implicated in the degeneration of sensory cells and endings of the hearing nerve which follows acoustic overstimulation. The NIDCD intramural Laboratory of Neurochemistry is studying intensely the molecular properties of the glutamate receptor family.

The NIDCD is supporting studies on the regeneration of sensory c cells. The first breakthrough in adult mammals occurred with the regeneration of vestibular hair cells. Most recently, investigators have demonstrated hair cell regeneration in the culture of tissue removed from the human inner ear. Continued research in sensory cell regeneration could provide much needed progress in the amelioration of sensory

hearing loss and tinnitus. This first breakthrough in human hair cell regeneration must be exploited quickly for the benefit of millions of hearing-impaired Americans.

Similarly, studies of smell and taste sensory cell regeneration may play a major role in research on the therapeutic repair of the central nervous system. Recent olfactory (smell) sensitivity research demonstrated in individuals with genetically determined specific anosmia (loss of sense of smell) the induction of olfactory sensitivity by repeated exposure to a specific odor. This finding would suggest a stimulus-induced plasticity in a sensory receptor neuron and a novel form of gene expression. This concept opens a new area of molecular biologic research and provides a basis for a new form of treatment.

Intramural scientists of the Voice and Speech Section have led in developing new treatments for patients with neurogenic voice disorders. They also introduced the first human use of botulinum toxin Type F for spasmodic dysphonia. Its injection on one side of the voice box results in muscle effects on both sides suggesting central nervous system changes. The physiologic bases for these changes are now being studied.

Application of modern technology to speech assessment is allowing investigators to examine trigeminolaryngeal reflexes in stuttering, physiological correlates of stuttering, developmental trends in childhood stuttering, and stuttered and disordered phonology in young children.

Studies of language and cognitive development in retarded children have previously indicated that language ability tends to be at or below other cognitive domains. Recent studies of children with Williams syndrome [WMS], conducted by NIDCD-supported scientists, have challenged the tenet that language is constrained and paced by cognitive skills. WMS, a rare genetic disorder, is characterized by mental retardation and distinctive facial features, cardiac and dental anomalies, and an excess of calcium in the blood causing fatigue, muscle weakness and depression. Additionally, WMS children have a most interesting and unique behavioral profile: linguistic abilities selectively developed in the face of severe general cognitive deficits. When compared with Down syndrome children, young children with WMS have a different cognitive phenotype, showing retardation in all developmental milestones, including language. Although young WMS children and children with Down syndrome are remarkably similar in their profound and equivalent delays, they follow different trajectories of development to adolescence, at which point they exhibit dramatically different language skills. WMS adolescents have relatively well developed semantic abilities. This research is examining differences between the two groups and analyzing language development in order to explain the contrasts between the two groups exhibited in adolescence. These studies are expanding our understanding of brain and behavior relations.

The NIDCD has begun the Partnership Program, a comprehensive minority research and training demonstration program with academic centers which have large enrollments of minority persons under-represented in biomedical and behavioral research. Students who are deaf or hard of hearing are also underrepresented in biomedical and behavioral research. Through a Memorandum of Understanding between the Office of Research on Minority Health and the NIDCD, this Partnership Program will provide support for improvement of curriculum and current research activities in the academic centers, and for the exchange of students, scientists, and administrators in order to maximize the opportunities for underrepresented persons to participate in fundamental and clinical research in human communication. These academic centers are: The Morehouse School of Medicine/Atlanta University Complex; University of Alaska System; University of Puerto Rico; and Gallaudet University.

Now that the NIDCD is five years old, there is a steady flow of impressive and significant research in each of the seven program areas. NIDCD support has stimulated training. Both extramural and intramural research opportunities have been created, and those training opportunities are in basic laboratories and in clinical settings. The National Multipurpose Research and Training Centers are thriving examples of what happens when one integrates outstanding scientists into a team, extends training opportunities and provides regional resources for the public. The NIDCD fifth anniversary was a moving celebration of science. Investigators presented the newest, the best science and, importantly, gave force and direction for the future. The NIDCD is fulfilling a promise to improve life for 46 million Americans who are challenged by disorders of hearing, balance, smell, taste, voice, speech or language.

Mr. Chairman, the 1995 budget request is \$167,129,000.

Mr. Chairman, I would be pleased to try to answer any questions you have.

BIOGRAPHICAL SKETCH OF DR. JAMES B. SNOW, JR.

Born: March 12, 1932, Oklahoma City, Oklahoma.

Marital status: Married, three children.

Education: B.S., University of Oklahoma, Norman, Oklahoma, 1949-52; M.D., Harvard Medical School, Boston, Massachusetts, 1952-56.

Professional history: Intern in Surgery, Johns Hopkins Hospital, Baltimore, MD, 1956-57; Resident in Otolaryngology, Massachusetts Eye and Ear Infirmary, Boston, MA, 1957-60; Captain, Consultant in Otolaryngology; U.S. Army Medical Corps, 8th U.S. Army, 121st Evacuation Hospital, Korea, 1960-61; Otolaryngologist, U.S. Army Hospital, Fort Leonard Wood, MO, 1961-62; Assistant Professor and Vice-Chairman, Department of Otorhinolaryngology, University of Oklahoma Medical Center, Oklahoma City, OK, 1962-64; Professor and Head, Department of Otorhinolaryngology, University of Oklahoma Medical Center, Oklahoma City, OK, 1964-72; Professor and Chairman, Department of Otorhinolaryngology and Human Communication, University of Pennsylvania, School of Medicine, Philadelphia, PA, 1972-90; Director, National Institute on Deafness and Other Communication Disorders, Bethesda, MD, 1990-present.

Society affiliations: Alpha Omega Alpha; American Academy of Facial, Plastic and Reconstructive Surgery; American Academy of Otolaryngology—Head and Neck Surgery; American Association for the Advancement of Science; American Broncho-Esophagological Association; American College of Surgeons; American Laryngological Association; American Laryngological, Rhinological and Otolological Society; American Medical Association; American Neurotology Society; American Otolological Society; American Society for Head and Neck Surgery; Association for Research in Otolaryngology; Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum; International Bronchoesophagological Society; Massachusetts Eye and Ear Infirmary Alumni Association; New York Academy of Sciences; Pan American Association of Otolaryngology and Broncho-Esophagology; Phi Beta Kappa; Sigma Xi; Society for Ear, Nose and Throat Advances in Children; Society of University Otolaryngologists—Head and Neck Surgeons.

Honors and awards: Regent's Award for Superior Teaching, University of Oklahoma, 1970; Certificate of Award, American Academy of Ophthalmology and Otolaryngology, 1971; Honorary Master of Arts, University of Pennsylvania, 1973; Second Vice-President, American Academy of Ophthalmology and Otolaryngology, 1973-74; Consulting Professor, Shanghai Second University of Medical Sciences, Shanghai, People's Republic of China, 1985; Honorary Fellow, Japan Broncho-Esophagological Society, 1985; Golden Award of the International Federation of Oto-Rhino-Laryngological Societies, 1989; Society of Scholars, Johns Hopkins University, 1991; and Honorary Member, Association of Otolaryngologists of India, 1992.

Senator HARKIN. We would like to know what is happening to tinnitus. What kind of progress is being made in that area? We do not have time now.

Dr. SNOW. All right, very good.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HEARING AID DEVELOPMENT INITIATIVES

Question. Please outline the progress that the Deafness Institute, in collaboration with the Department of Veterans Affairs, has made in its efforts to advance hearing aid research and development.

Answer. Following a meeting of thirteen experts in the area of hearing aid research and development in July, 1992, the NIDCD and the Department of Veteran Affairs [DVA] selected several priority areas for development. A formal Memorandum of Understanding for Collaboration in Hearing Aid Research was signed in August of 1992. Five initiatives have been developed and are in various stages of implementation. An Ad Hoc Advisory Committee on Hearing Aid Research and Devel-

opment was convened on July 23, 1993 to provide advice about each of the initiatives. These initiatives include a program announcement to encourage the submission of grant proposals to determine how hearing aids affect speech understanding in quiet and in noise that was published in January, 1994 and a program announcement for research to determine ways to measure the benefit received from hearing aids, also to be published in 1994. A request for proposals for the design, development, and evaluation of speech processing strategies for hearing aids, referred to as a program of device development for hearing aids, is scheduled for issuance in 1994. Clinical trials are expected to begin in fiscal year 1995 through an interagency agreement with the DVA. The clinical trials will allow for the determination of subgroups of hearing-impaired individuals who benefit most from existing and newly developed hearing aid technologies. A clinical trial protocol writing committee has met twice, once in September of 1993 and again in February of 1994. The protocol will be available by May of 1994. A series of hearing aid research and development conferences, the first to be held in September of 1995, will serve as national biennial forums for the presentation of research relevant to hearing aids. A planning committee met in January of 1994 to provide guidance regarding this important meeting.

SENSORY CELL REGENERATION

Question. Investigations into sensory cell regeneration may play an important role in the restoration of hearing. What advances has the NIDCD made in the area of sensory cell regeneration, and what does the Institute hope to achieve in the near future?

Answer. The sensory epithelium or hair cells of the inner ear initiate the signals to the nervous system which are involved in balance and hearing. NIDCD-supported investigators have previously shown that damaged inner ear hair cells can regenerate in a nonmammalian model (birds). While it was initially thought that mammalian inner ear hair cells had no regenerative ability, NIDCD-supported investigators have recently shown that human vestibular hair cells demonstrate some regenerative capacity. This provides a possible explanation for the recovery of balance function in patients exposed to ototoxic, or ear-damaging, drugs. Current work is focusing on what chemical factors in the vestibular epithelium are involved in initiating cell regeneration. Given the similarities between hair cells in the auditory and vestibular systems, work can then focus on determining if the failure to find auditory hair cell regeneration is due to the lack of one or more of these "triggering factors." Once the factors which can initiate inner ear hair cell regeneration are defined, then approaches to deliver these substances into the inner ears of individuals with hearing impairment can be devised. The NIDCD's interest in receiving proposals addressing this technique was recently published in the form of a program announcement.

TINNITUS RESEARCH

Question. What kind of progress is being made in the area of tinnitus research?

Answer. Tinnitus is a condition that afflicts 15 to 20 million Americans. A significant number of whom are precluded from normal occupational and social activities by the tinnitus. The pathological conditions which are known to produce the symptom of tinnitus affect different levels of the auditory system, including peripheral and central components. Thus, information gained from research on virtually any aspect of the auditory system will potentially be applicable to understanding some forms of tinnitus. Research progress which helps to ameliorate or eliminate tinnitus will have a significant public health impact, both socially and financially. The current challenge facing the NIDCD is to assist the scientific community in integrating our current knowledge of the auditory system with state-of-the-art research on potential origins of tinnitus and on formulation of new testable hypotheses for clinical trials of efficacy of therapy for tinnitus.

Both basic and clinical research approaches are being taken to attack the problem of tinnitus. One NIDCD-supported investigator has developed an animal model for tinnitus, an important first step in studying the basic mechanisms of this often-debilitating condition. These animals appear to perceive sound in a quiet environment after ingestion of ototoxic drugs, which are known to produce tinnitus in clinical situations. This work allows the exploration of the origin of these pharmacotherapeutically induced forms of tinnitus. Current findings suggest that altered calcium flux or release in the cochlea appears to play a role in the generation of "tinnitus-like" symptoms in animals. Decreases in inner ear fluid calcium are correlated with the induction of salicylate- or quinine-induced tinnitus; prevention of changes in inner ear fluid calcium through dietary calcium supplementation or

administration of calcium channel blockers (a class of drugs) reverses the tinnitus-like behavior. Other investigations have reported the presence of alterations in inner ear fluid calcium in Meniere's disease, a disorder which affects hearing and balance and also has tinnitus as a symptom. These data underscore the potential applicability of other basic research in auditory and vestibular disorders to the study of tinnitus.

Clinical research in tinnitus currently supported by the NIDCD includes the development of methods to measure the intensity of tinnitus experienced by an individual, knowledge that may be necessary for the study of the efficacy of therapy for tinnitus. Understanding the physical characteristics of the apparent sound detected by individuals with tinnitus is also important, since there is evidence that tinnitus associated with some forms of sensorineural hearing impairment has the characteristics of a complex sound, rather than a pure tone. It is possible that the different underlying causes of tinnitus could each produce a distinctive complex of waveforms. NIDCD-supported investigators are now attempting to construct waveforms which match the tinnitus found in individuals with different causes of hearing impairment. This will permit a classification of tinnitus based on the perceived sound, which may correlate with common defects for each class and lead to the development of strategies for reducing or neutralizing the perceived sound.

The NIDCD will hold a workshop on tinnitus in fiscal year 1995. This workshop will bring together the foremost scientists in many areas of auditory research to analyze the current state of research in tinnitus and to suggest new strategies for tinnitus research.

QUESTIONS SUBMITTED BY SENATOR HATFIELD

CLINICAL RESEARCH

Question. Dr. Snow, as a follow-up to my earlier questions on the record, would you provide to the Subcommittee the division of your research and project grants between "basic" and clinical? How do you define clinical research?

Answer. The NIDCD grant portfolio for fiscal year 1993 represents approximately 54 percent basic research and 46 percent clinical research. Clinical research is defined as those research projects involving human subjects.

HEARING AID DEVELOPMENT INITIATIVE

Question. Dr. Snow, would you provide the Subcommittee with a copy of the survey completed in 1992-93 which investigated the nature of hearing aid research and a copy of the program announcement on the understanding of speech and hearing aid? Is this program announcement limited only to the unilateral fitting of hearing aids or does it also include bilateral fittings? Please explain.

Answer. The NIDCD and DVA sponsored a Hearing Aid Research Workshop on July 17, 1992 at the NIH in Bethesda, Maryland. This workshop was asked to survey the current status of hearing aid research and to recommend research strategies for the future. The workshop was designed to identify research to be supported through the federal government grant and contract mechanisms, with the ultimate goal of improving available hearing aid strategies and technologies for hearing-impaired persons. Representatives from the NIDCD and DVA, together with 15 invited scientists, attended the workshop. Participants were selected to represent a broad spectrum of scientific disciplines and expertise in auditory amplification/prosthetic technology. Although no formal report of the July 1992 Hearing Aid Research Workshop was produced, the highlights of the discussion of that meeting are briefly summarized here. Recent accomplishments and research priorities were discussed by the participants. Several recent advances in hearing aids were described and included: (1) the miniaturization of circuits such that sophisticated signal processing can be placed in small wearable units; (2) the development of digital signal processing techniques using relatively low power demands that can be fitted into wearable units; and (3) the use of multiple-microphone arrays. The hearing aid research priorities that were identified at the hearing aid workshop included: (1) basic studies of auditory processing and speech perception as they relate to hearing impairment, (2) a program of directed device development, (3) outcome measures for amplification benefit, (4) characterization of auditory and nonauditory individual capabilities relevant to hearing aids, (5) signal processing, such as microphone arrays, to improve speech understanding in quiet, noise and reverberation, (6) evaluation of existing and development of new binaural hearing aids, (7) development of coding strategies for severely hearing-impaired individuals, (8) program of hearing aid research for children—special issues, (9) special needs of the elderly and individuals with multiple

disabilities, (10) improved hardware, (11) enabling technologies, (12) development of new clinical tools for prescriptive fitting of hearing aids. A common theme among all initiatives was to allow for technology transfer, training, and basic science studies.

All of our five hearing aid research initiatives were greatly influenced by the information garnered from this important workshop. Indeed, the two program announcements, "Effects of Signal Processing on Speech Understanding in Quiet and in Noise" and "Evaluation Endpoints for the Determination of Hearing Aid Benefit for Hearing-Impaired Persons" are directly related to the first and third research priorities outlined above; the request for proposals "Program of Hearing Aid Device Development" is directly related to the second research priority outlined above; the first question to be addressed in the first clinical trial was proposed largely based on discussions at this workshop; and the planning of the first Hearing Aid Research and Development Biennial Conference has also taken into account the recent accomplishments and research priorities identified by the workshop participants.

The program announcement on the understanding of speech with a hearing aid is included. Research applications responsive to this program announcement could include studies of unilateral or bilateral fittings of hearing aids, or both. The program announcement encourages studies designed to assess the responses of those with and without hearing loss to sounds processed through hearing aids, in conditions normally encountered by hearing aid users. Focus will be placed on the use of noises and other conditions representative of real listening environments.

HEARING AID WORKSHOP SUMMARY AND HIGHLIGHTS

The National Institute on Deafness and Other Communication Disorders [NIDCD] and the Department of Veterans Affairs [DVA] sponsored a Hearing Aid Research workshop on July 17, 1992 at the NIH in Bethesda, Maryland. This workshop was designed to identify research to be supported through the federal government grant and contract processes, with the ultimate goal of improving available hearing aid strategies and technologies for hearing-impaired persons. Representatives from the NIDCD, the DVA and 15 invited scientists attended the workshop. Participants were selected to represent a broad spectrum of scientific disciplines and expertise in auditory amplification/prosthetic technology. Recent accomplishments and research priorities were discussed by the participants, and highlights of their discussion are presented below.

Recent developments

Significant advances have been made in hearing aid signal processing. One such advance has been in the area of multiple-microphone arrays, which allow the environment to be sampled at multiple points. Both fixed and adaptive schemes have shown improvements in hostile noise environments. This technology, however, has not been commercialized, largely due to cosmetic concerns. Significant advances have also been made in the areas of low-power circuits, digital signal processing, multiband compression, real-ear measures, and in the control of the acoustic signal delivered to the ear. Programmable aids provide more flexibility and opportunity for adjustment than was previously available. Consumers have realized significant improvements in hearing aid cosmetics. Smaller, more cosmetically appealing in the ear [ITE] and behind the ear [BTE] hearing aids are now widely available. Advances made in speech processing with cochlear prostheses show promise for incorporation into more traditional hearing aid technology and fitting practices.

RESEARCH PRIORITIES

Basic studies of auditory processing and speech perception re: hearing impairment, including listening at high signal levels

The information-bearing parameters and units of speech are not yet fully understood nor are the effects of hearing loss on the perception of these parameters. It is also not known how the normal ear reacts to sound presented under conditions encountered by individuals with hearing impairment (e.g. suprathreshold, reduced the frequency bandwidth). Even less well understood is how both the normal and impaired auditory systems perform under the conditions imposed by the signal-processing technology of amplification devices. Improved understanding of the theoretical and practical issues of the physiologic, perceptual and communicative worlds of hearing-impaired persons is needed. Understanding individual differences in speech perception and determining the salient speech cues under conditions that are relevant to amplification and separating audibility effects from other aspects of speech perception is also required.

Program of directed device development

A program of directed device development would support the design and evaluation of new processing strategies for hearing aids. An important fiscal aspect of such a program would be the sequencing of projects. First, all or a number of novel ideas and principles of processing strategies should be evaluated in a laboratory-based initial screening stage, with well-defined criteria, prior to any consideration of clinical or field trials. Second, enabling technology would then be in place for field evaluation of only the most promising strategies. It is likely that many strategies will undergo evaluation before the most promising ones are identified. The physiology of hearing impairment, with particular attention to the heterogeneity of hearing impairment, should be incorporated into the design of the processing strategy. Additional desirable features of a program of directed development would include the development of an infrastructure, providing hardware to support field evaluation, and identifying a team of scientists, whose principal goal would be to integrate findings from all funded NIDCD projects in the hearing program.

Outcome measures

Both basic and applied research studies on the evaluation of amplification benefit are needed. Measures which are most appropriate for defining benefit have yet to be determined so multiple measures of benefit need to be explored. For example, is the appropriate outcome measure a score of intelligibility? Is it a loudness comfort level? Is it subjective or objective? Is it dependent upon the environment and therefore dynamic? Is listener effort the most important variable for success?

There are multiple measures of benefit, those used for research studies and distilled versions used for more rapid routine clinical practice. Both temporary and final measures are used in evaluative processes. Temporary measures, otherwise known as surrogate endpoints, serve as interim indicators, allowing research to advance at a faster pace than if one waited for the final outcome. These surrogate endpoints are intended to be either related to or somehow predictive of the final endpoint. Final endpoint is the ultimate outcome measure which is usually obtained only after considerable time and expense. A 2 x 2 matrix of clinical and research trials and temporary and final endpoints remains to be completed. Included in the umbrella of outcome measures is the ability of clinical/research measures to predict field trial outcome. Determining the most appropriate field trial measures and predictive measures of field trial outcome remains to be done.

Characterization of auditory and non-auditory individual capabilities relevant to hearing aids

Characterization of individual auditory performance relative to hearing aid selection and processing parameters is long overdue. Auditory abilities "beyond the audiogram" must be understood and measured on an individual basis. The intent is to move away from classification of hearing loss and to focus on individual performance measures. Group classification of hearing loss, as has long been the practice, reduces the utilization of subtle differences in residual auditory ability. The development of materials, tools, and instruments for characterizing auditory capabilities and individual "audibility" must be supported, yielding individual fitting and processing schemes. Auditory capabilities to be understood for hearing aid selection, fitting, and rehabilitation include both threshold and suprathreshold measures. Measurement of non-auditory abilities and psychosocial factors and the interaction of other senses, including vision, may also be useful. Trading relationships, such as value judgments of acoustic benefit vs size, may also be of relevance. A matrix of auditory, and non-auditory capabilities, and relevant and non-relevant parameters is at issue.

Signal processing, such as microphone arrays, to improve speech understanding in quiet, noise and reverberation

Improving speech understanding through hearing aids in quiet, noise and reverberation is critical. This can only be achieved through advances and improvement in signal processing. The ability to hear in the presence of background noise, long a problem with hearing aid users, must be aggressively addressed. While the means for improving performance is not known, it is known that removing noise helps, and it is felt that the reduction of noise would provide a quantum leap in hearing aid development. Improving signal to noise ratios through signal processing strategies, such as multiple microphone arrays, remote microphones, directionality techniques, or suppression techniques, continues to be an important goal. Adaptability of devices, reacting to changes in input signal and environment, as well as to the changing needs of the listener, must also be considered.

Evaluation of existing and development of new binaural hearing aids

Binaural hearing aids have not been widely utilized by the consumer. Empirical evidence for stereophonic benefit is lacking, allowing "cost-benefit" concerns to remain at issue. The development and evaluation of new binaural aids should be encouraged, as should differential evaluation methods designed to define the advantages and disadvantages of monaural vs binaural hearing aids. Head shadow effects, binaural masking level differences, binaural summation and stereophony effects require further research, as do issues related to central nervous system atrophy/maintenance with hearing aid use. While there is some evidence of the benefits of binaural aids for certain hearing losses, the available data is lacking with respect to defining the individual auditory characteristics required for beneficial utilization of binaural aids. The added economic burden of binaural aids must be justified for the individual user based on the specifics of his or her auditory abilities and needs.

Development of coding strategies for individuals who have severe hearing impairments

Effective acoustic coding strategies are needed for persons who have limited auditory capabilities. The acoustic signal should be used to generate new patterns and coding/recoding strategies that can be handled by the impaired system. An optimal coding strategy may be either natural or non-natural.

Program of hearing aid research for children: Special issues

Although the needs of children wearing amplification are different from the needs of adults, these needs are often overlooked. Since children have no apriori expectations of speech, new speech coding strategies may be possible. These strategies may deviate from "natural" by creating "unnatural" by optimal processing for children. These same coding strategies, based on an "acceptability" rating, may not be acceptable for adults. The plasticity of the adolescent and adult auditory system should be further explored. Practical, theoretical, and ethical issues must be addressed regarding the proper prosthetic design for use by children. Both auditory and nonauditory abilities should be evaluated in children on an individual developmental basis. The transfer of technology to children may be different than for adults. Evaluative tools (i.e. outcome measures) may be drastically different for children and adults based on temporal factors of development as well as the limited ability of children to provide subjective feedback. Finally, special needs for delivery, support and rehabilitative services as they relate to children require further definition.

Special needs of the elderly and multi-handicapped

The elderly often comprise the largest group of hearing aid users with unique needs in the areas of hearing aid technology and users service delivery. There is a large segment of this population who are appropriate hearing aid candidates but who are not hearing aid users. Reexamination of the endpoint is warranted; i.e. if the peripheral and central auditory system is severely compromised, high technology may not be warranted. Alternately, there are many older persons with mild hearing losses who could receive benefit from appropriately designed hearing aids. These issues as related to elderly persons, as well as to individuals who have multiple disabilities, deserve further consideration.

Transducers, acoustic impedance, and feedback control

More efficient low noise transducers are needed for better hearing aid performance. Solid state technology, addressing bandwidth, impedance and complexity in assembly issues should be pursued. Better coupling (both input and output) to the concha and ear canal is needed and should be designed to minimize and control feedback. Magnetic coupling to the tympanic membrane, pinna gain effects, and occlusion effects are also areas of inquiry. Hearing aids should provide a level of quality acceptable to persons with no auditory deficits prior to their expected acceptance by persons with assorted auditory deficits.

Enabling technologies, such as low power VLSI circuit designs, battery technology, new electroacoustic coupling technologies, RF links and implantable devices

Development of new hardware for hearing aids will provide the enabling tools needed for determination of the requirements for improved hearing aids. These enabling technologies also provide the platform for improvements in processing schema and provide the hardware for field trials. Hardware that is portable, has low power needs, and is programmable is needed for field trials as new processing strategies emerge from the laboratories and clinics. Other areas of inquiry include headphone/coupler techniques, standardized metrics, improved chip circuitry, programmable digital signal processing, and changeable filter coefficients.

Development of new clinical tools for prescriptive fitting of hearing aids

Most prescriptive fittings to date use frequency gain characteristics almost exclusively. Current fitting schema are not keeping pace with the latest available technology, such as compression, multichannel or programmable aids. The development of new clinical tools for improved prescriptive fitting is required. Areas of inquiry include: new appropriate fitting strategies, outcome measures or fitting strategies, new generation speech tests and their ability to provide predictive information, training and longitudinal effects on fitting strategies, and ways of subdividing population of persons with hearing impairment for research on fitting strategies while recognizing the heterogeneity of this group. Another area of concern is that the current transfer of technology to the clinical setting for implementation in evaluation and fitting is minimal. As technology becomes more complicated and advanced, this transfer of information becomes not only more critical, but also more difficult. Finally, objective measures of efficacy, suitable for children and adults, must be designed.

Common themes among all initiatives: Technology transfer, training, and basic science studies

Means for technology transfer must be in the framework of all initiatives in order to achieve the stated goals for advances in hearing aid design, fitting and rehabilitation. Technology transfer from the laboratory to the clinic and industry is required in a manner understandable to the audience. Likewise, clinical needs and industrial limitations need to be communicated to the research laboratory.

Since the goal is to implement research findings in the clinic, multidisciplinary training is needed for users, clinicians, engineers and research scientists in order to facilitate this technology transfer. Furthermore, innovative creative ideas to help improve hearing aid delivery and technology should be encouraged. Evaluation of these principles will become the standard of comparison for newly promoted ideas.

Effects of signal processing on speech understanding in quiet and in noise

NIH Guide, Volume 23, Number 3, January 21, 1994, PA number: PA-94-030, P.T. 34; K.W. 0715055, 0775005, 0740030.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Purpose

The National Institute on Deafness and Other Communication Disorders [NIDCD] invites applications for support of research addressing the effects of signal processing on speech understanding in quiet and in noise. The goal of this Program Announcement [PA] is to stimulate basic research in a wide range of scientific disciplines to increase our understanding of normal and impaired auditory systems' responses to speech sounds that are processed through hearing aids, especially in the presence of background noise. This information will ultimately help to guide the development of improved hearing aids.

Healthy People 2000

The Public Health Service [PHS] is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Effects of Signal Processing on Speech Understanding in Quiet and in Noise, is related to the priority area of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

Eligibility requirements

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply for the First Independent Research support and Transition [FIRST] (R29) award. Applications from minority individuals and women are encouraged.

Mechanism of support

Support mechanisms appropriate for this announcement include the individual research project grant (RO1) and the FIRST (R29) award.

Research objectives

Background.—Hearing aids continue to be the principal management of choice for most people with sensorineural hearing loss. Unfortunately, hearing aids often provide limited benefit, especially in noisy conditions. Progress in the miniaturization of circuits and transducers now allows a wide range of signal processing functions to be incorporated into very small devices. Many of these processing functions may improve the understanding of speech in noisy environments. However, the increased signal processing potential of hearing aids may soon surpass, or has already surpassed, the basic understanding of audition required to utilize the technology optimally. For example, the information-bearing acoustic parameters and units of speech are not yet fully understood. Nor is it known how the characteristics of hearing impairment (e.g., reduced or altered spectral and temporal processing abilities, increased linearity of the auditory system) affect the perception of various speech parameters. Even less well understood is how both normal and impaired auditory systems perform under the conditions imposed by the signal processing technologies of hearing aids (e.g., listening at high intensity levels, increased masking, temporal and spectral changes in signals).

Studies designed to investigate the problem of hearing in noise date back to the early development of hearing aids. Numerous studies have confirmed that, in contrast to individuals with normal hearing, hearing-impaired subjects perform poorly on speech intelligibility tasks in noisy conditions. The cause of that poor performance has yet to be defined adequately. Early studies have shown that both frequency and temporal resolution are poorer in listeners with sensorineural hearing loss than in listeners with normal hearing. These differences are attributed to such factors as abnormal spread of masking, broader peripheral filtering, and longer time constants for recovery from forward masking. However, some recent studies also support the possibility that the effects attributed to deficits in frequency selectivity and temporal processing in hearing-impaired listeners may in fact result from abnormal rates of growth of response to acoustic stimuli in the impaired ear. In this view, underlying properties of auditory filters and time constants remain unaltered in the impaired ear, and recruitment becomes the primary phenomenon in abnormal suprathreshold response. Additionally, some data suggest that the hearing-impaired subjects' poor performance can be explained largely on the basis of differences in audibility due to decreased hearing sensitivity, masking effects, and/or speech presentation level.

Few studies have examined the effects of signal processing by hearing aids on audition using either normal or hearing-impaired subjects. It is probable that the difficulties in speech understanding experienced by individuals with sensorineural hearing losses, which are often associated with auditory processing abnormalities in addition to a loss of sensitivity, may be exacerbated by the high intensities of sound processed through hearing aids. It is proving to be difficult to predict how a given signal processing strategy or circuit, with high presentation levels and many changes in temporal and spectral characteristics, will process continually changing speech signals. Furthermore, the interaction of the processed acoustic signal with the remaining capabilities of the impaired auditory system has never been systematically explored. A more thorough understanding of the effects of signal processing on audition is needed in order to guide the development of and to allow the proper utilization of improved hearing aids. Similarly there is need for a better understanding of the theoretical and practical issues of the physiologic, perceptual and communicative processes of hearing-impaired persons under conditions relevant to the use of hearing aids.

Research goals and scope.—Studies are encouraged that are designed to assess the response of individuals with normal and impaired auditory systems to sounds that are processed through hearing aids, in the conditions normally encountered by hearing aid users. Noises and other experimental variables representative of real listening environments should be used when possible. The use of experimental designs that minimize the confounding effects of threshold and presentation levels on estimates of subject performance are desirable. Areas of research that would be responsive to this PA include, but are not limited to:

- Studies of the influences of processing speech through hearing aids (e.g., high presentation levels, changes in temporal and spectral characteristics) on the understanding of speech sounds in quiet and in noise for normal and impaired auditory systems;
- Studies in quiet and in noise designed to assess the interaction between the processed acoustic signal and the impaired auditory system having such features as reduced frequency selectivity, limited dynamic range, and abnormal growth of loudness;

- Studies of methods of predicting speech recognition with hearing aids in quiet and in noise for normal and impaired auditory systems;
- Studies designed to examine the relationship between optimal speech spectrum audibility and loudness tolerance under conditions relevant to hearing aid use in normal and impaired auditory systems in quiet and in noise;
- Studies of the effects of reverberation on speech recognition under conditions relevant to hearing aid use by normal and impaired auditory systems in quiet and in noise;
- Studies of changes in speech recognition performance as a function of intensity level with consideration of the factors involved in audibility in quiet and in noise in normal and impaired auditory systems;
- Studies of psychoacoustic performance measures (e.g., discrimination of spectral contrast, frequency resolution, sensitivity to subtle temporal factors within complex sounds) under conditions relevant to hearing aid use in normal and impaired auditory systems in quiet and in noise.

Study populations

Special instructions to applicants regarding implementation of NIH policies concerning inclusion of women and minorities in clinical research study populations.—NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in sections 1–4 of the Research Plan and summarized in section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

Application procedures

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the

application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7250. The title and number of the announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of references letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to: Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892.

Review considerations

Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

Award criteria

Applications will compete for available funds with all other approved applications. The following will be considered as funding decisions are made: quality of the proposed project as determined by peer review, availability of funds, and program balance among research areas of the announcement.

Inquiries

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be addressed to: Amy M. Donahue, Ph.D. or Lynn E. Huerta, Ph.D., Division of Communication Sciences and Disorders, National Institute on Deafness and Other Communication Disorders, Executive Plaza South, Suite 400-C, 6120 Executive Boulevard, Bethesda, MD 20892, Telephone: (301) 402-3458, FAX: (301) 402-6251.

Inquiries regarding fiscal matters may be addressed to: Sharon Hunt, Division of Extramural Activities, National Institute on Deafness and Other Communication Disorders, Executive Plaza South, Suite 400-B, 6120 Executive Boulevard, Bethesda, MD 20892, Telephone: (301) 402-0909, FAX: (301) 402-1758.

Authority and regulations

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

HEARING AID PROGRAM ANNOUNCEMENT

Question. Dr. Snow, under this program announcement, how are the proposals to be evaluated? Will the evaluation of the proposals be done by clinical research scientists? What plans do you have to translate successful clinical results into practice?

Answer. Research grant applications responsive to this program announcement will be evaluated through the regular NIH Division of Research Grants peer-review system. This well-respected system is designed to provide a fair but rigorous review of the scientific merit of a given application. Special attention is paid to assure that reviewers with appropriate scientific training and expertise are assigned to each application. Thus, if clinical research is proposed, clinical research scientists are typically assigned to review those applications. Successful clinical results will be translated into practice through presentations at meetings and publications by the investigators. Peer-review of research findings is also an important part of the research process. Transmitting findings from the laboratory into clinical practice will be facilitated by the initiation of the national interdisciplinary forum on hearing aid research and development.

HEARING AID DEVICE DEVELOPMENT

Question. Dr. Snow, I understand that under the "device development" program you have undertaken in collaboration with the Veterans Administration that the

field testing will be carried out in VA medical centers. What evidence is there that VA patients represent the types of hearing impairment characteristics of the population at large?

Answer. The program for hearing aid device development will be supported as a research and development contract and will not necessarily take place in a VA medical center.

The Clinical Trials will be conducted in selected VA medical centers. The draft protocol for the first clinical trial specifies that the subjects will be representative of the age, gender, minority status, and degree of hearing loss typical of the adult hearing-aid using public. The DVA has carried out similar research in the past and has mechanisms in place to recruit from outside the VA patient population to meet these requirements, if necessary. While we hope that the new hearing aid technologies and strategies developed under the contract for hearing aid "device development" will ultimately be included for evaluation in the hearing aid clinical trials to be carried out in the VA medical centers, the clinical populations tested initially will be those available to the investigators awarded the contract. These populations may or may not include VA patients, but will certainly adhere to the new "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research."

HEARING AID PROTOCOL

Question. Dr. Snow, would you provide the Subcommittee with a copy of the hearing aid development protocol once it is complete? Will the protocol give attention to the design of digital hearing aids?

Answer. A copy of the NIDCD/DVA Hearing Aid Clinical Trials Protocol can be provided to the Subcommittee once it is complete. We expect to have a final draft by mid-April. It will then be reviewed by the Ad Hoc Advisory Committee on Hearing Aid Research and Development. The advent of digital hearing aids is one of the most important recent advances in hearing aid research and development. Further refinements in the design and processing capabilities of digital hearing aids is expected to take place as a result of our hearing aid initiatives. This might take place under the contract for the design, development, and evaluation of speech processing strategies for hearing aids or it might take place through our investigator-initiated research grants, including the Small Business Innovation Research (SBIR) program. After the fundamental questions about linear versus compression amplification are answered in terms of which subgroups of the hearing-impaired population benefit from which strategies and technologies and under what circumstances, digital technology will be evaluated as a part of the determination of which forms of compression technology benefit which subgroups of the hearing-impaired population and under what circumstances.

HEARING AID DEVELOPMENT INITIATIVE

Question. Dr. Snow, I understand that the presence of ringing feed-back is a frequent problem with hearing aid users. Is this problem to be considered in connection with the hearing aid development initiative?

Answer. Although feedback remains a common complaint of many hearing aid users, technologic advances have been made to help alleviate this annoying problem. For example, a NIDCD-supported scientist has recently shown that by physically delivering sound deeper into the ear canal via improved hearing aid shell designs, all of the subjects tested reported improved feedback control. In addition, most of the subjects also showed reduced occlusion effects, another common complaint of hearing aid users, most often described as "hollowness" or a feeling of "talking inside a barrel". This work was supported through our SBIR program and should be available to the commercial market pending further development.

Question. Dr. Snow (NIDCD), as we discussed at the hearing I am interested to know what progress has the Institute made on the hearing aid development initiative begun with the Department of Veterans Affairs? What are the levels of activity estimated for fiscal year 1994 and projected for fiscal year 1995?

Answer. Following a meeting of thirteen experts in the area of hearing aid research and development in July, 1992, the NIDCD and the DVA targeted several priority areas. A formal Memorandum of Understanding for Collaboration in Hearing Aid Research was signed in August of 1992. Subsequently, five initiatives were developed and are in various stages of implementation. An Ad Hoc Advisory Committee on Hearing Aid Research and Development was convened on July 23, 1993 to provide advice about each of the initiatives. These initiatives include a program announcement to encourage the submission of grant proposals to determine how hearing aids affect speech understanding in quiet and in noise that was published in January, 1994 and a program announcement for research to determine ways to

measure the benefit received from hearing aids, also to be published in 1994. A request for proposals for the design, development, and evaluation of speech processing strategies for hearing aids, referred to as a program of device development for hearing aids, is scheduled for issuance in 1994. Clinical trials are expected to begin in fiscal year 1995 through an interagency agreement with the DVA. The clinical trials will allow for the determination of subgroups of hearing-impaired individuals who benefit most from existing and newly developed hearing aid technologies. A clinical trial protocol writing committee has met twice, once in September of 1993 and again in February of 1994. The protocol will be available by May of 1994. A series of hearing aid research and development conference, the first to be held in September of 1995, will be national biennial forums for the presentation and discussion of hearing aid research and development. A planning committee met in January of 1994 to provide guidance regarding this important meeting.

The NIDCD expects to spend an estimated \$6.3 million principally on hearing aid research projects in fiscal year 1994. In addition, \$400,000 will be provided for the program for device development late in fiscal year 1994. In fiscal year 1995 the clinical trial will require an additional \$750,000. Two new grants related to advancing hearing aid signal processing capabilities have been funded during fiscal year 1993. Both research projects are addressing the most common complaint of hearing aid users, that of the difficulty of understanding speech in noise, using another of the most promising technologies available, multiple microphones. Each laboratory is using an unique but complementary approach to applying this technology to the problem, and the results are expected to advance this technology so that clinical trials for assessing multiple microphone array hearing aids can take place. In addition, NIDCD has just awarded an SBIR Phase I grant designed to develop another approach to multiple-microphone hearing aids.

NATIONAL INSTITUTE ON MENTAL HEALTH

STATEMENT OF REX W. COWDRY, M.D., ACTING DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Cowdry, the Acting Director, National Institute on Mental Health.

Dr. COWDRY. In deference to my colleagues, I will try to keep my remarks within the 90-second mark.

You are well aware of the remarkable complexity of the human brain and mind and of the societal burdens that are posed by mental illness. The short answer to your question, what would NIMH do with a 50-percent increase, would be to present our council's four strategic plans and pile them up on the table to give you some sense of what that increase would produce. The increased appropriation would raise our success rate, with the 4-year phase-in that you mentioned, from 20 percent to 30 percent.

Let me give you an example of the research findings from our plans in schizophrenia and the Decade of the Brain. We have combined elements of those two plans in centers for neuroscience and severe mental illness. A finding has emerged from one of those centers that suggests that schizophrenia is associated with a developmental anomaly of the brain where neurons migrate abnormally during early development. The origin of this is unclear.

I believe you are also aware of the human brain project, which calls for a map of the information superhighway that each of us holds within our skull. Child and adolescent mental health and disorder research also is vitally needed and is a seriously underdeveloped area addressed in the third strategic plan.

PREPARED STATEMENT

Finally, the services research plan has provided Congress with a demonstration that our treatments for severe mental illness are both effective and cost effective. Equitable treatment for mental illnesses can actually save money.

Thank you. In deference, I will stop at that point.

[The statement follows:]

STATEMENT OF DR. REX W. COWDRY

It is my pleasure to appear before you to discuss the research efforts of the National Institute of Mental Health [NIMH] and, in particular, to report on our progress in addressing the priorities recommended by Congress and our Advisory Council.

Before I begin, Mr. Chairman, let me note that I am delivering this statement not only for NIMH, but also for the Institute Director, Dr. Frederick K. Goodwin, who will soon be leaving the Institute to establish a Center on Science, Medicine, and Human Values. In addition to recognizing Dr. Goodwin's distinguished 29-year career in research and mental health leadership, it is a special pleasure to note that he was my original research mentor when I came to NIMH 17 years ago. The field,

and persons with mental illness, are enormously grateful for Dr. Goodwin's many contributions.

The President's fiscal year 1995 budget request for the NIMH responds to urgent needs to address the causes, treatment and prevention of mental illnesses which, in any given year, affect one-fifth of the population and produce substantial disability in half of those affected. From individual to society, from infancy to old age, mental illness confounds, disables, and impoverishes patients and their families alike. It is also very costly to our Nation, with direct and indirect costs estimated at \$148 billion per year, including 25 percent of all Federal disability payments. Yet, as research has shown, mental illnesses are definable; they are increasingly treatable in a cost-effective manner; and some are preventable.

These advances are exciting for those of us whose lives have been devoted to unlocking the mysteries of the brain. They are equally exciting for those of us who each day treat the unique suffering associated with mental illness. But they are most exciting for those of us who are directly affected by mental illnesses—my own extended family has been visited by major depressions and by suicide.

A scientific focus on understanding, treating, and preventing mental disorders is the defining mission of the NIMH. As our Nation enters the second half of the Decade of the Brain, NIMH's scientific accomplishments already have begun to develop a new level of understanding of the brain and behavior—understanding that is being applied to alleviate human suffering. Neuroscience, an area of interdisciplinary research focused on how specific brain functions (or dysfunctions) relate to particular behaviors, has made remarkable advances in exploring the human brain. Behavioral research has made substantial progress exploring the factors which shape our interactions with the world, and has demonstrated an ability to improve the lives of many of our citizens. In particular, it has demonstrated an ability to change behaviors that put some of our citizens at increased risk for developing AIDS. Psychopharmacologic research has advanced our understanding of the effects of drugs and their role in treating mental illnesses. And a concerted effort in the area of services research is improving our ability to reach those who need treatment for mental illnesses and to do so in the most effective and cost-effective manner.

To illustrate the breadth of the Institute's efforts in understanding mental illnesses, efforts spanning basic neuroscience, clinical pathophysiology, and treatment efficacy and effectiveness studies, I would like to focus my remarks primarily on new findings from NIMH-funded research on schizophrenia, the most chronic and disabling of the severe mental disorders and one of the most formidable challenges to psychiatric science. Typically, the major symptoms of schizophrenia appear in late adolescence or early adulthood. These include both the "positive" symptoms of hallucinations, delusions, and bizarre thought patterns that typically lead to psychiatric treatment and hospitalization, and the "negative" symptoms of social isolation and withdrawal. The illness tends to first appear just as adult life begins, shattering career plans, ending relationships, and tormenting those directly affected and their families and friends. More than 2 million Americans have schizophrenia in any given year.

Today, I am able to report that an increasing number of investigations point with remarkable consistency to the likelihood that schizophrenia is the manifestation of an abnormality in brain development. Strong evidence for such an abnormality is found in studies of post-mortem tissue of brains from individuals with schizophrenia. Investigators working at an NIMH-supported Center for Neuroscience and Schizophrenia have found that particular populations of neurons normally found in the outer layers of the prefrontal cortex were concentrated instead in deeper layers of the cortex on patients with schizophrenia, suggesting that these neurons had not completed their migration during brain development and may not have made the appropriate connections between the prefrontal cortex and the rest of the brain. This developmental abnormality corresponds anatomically to previous reports of reduced activity in the prefrontal cortex in schizophrenia demonstrated by brain imaging.

One of the enduring puzzles of schizophrenia is the appearance of the disease long after the presumed developmental injury. Intramural researchers have now developed a novel animal model in which very early injury to one part of the brain, the hippocampus, produces behavioral abnormalities which are only evident when the animal approaches adulthood. These behaviors correspond to behavioral abnormalities produced by adult lesions in prefrontal cortex and elicited by the release of the neurotransmitter dopamine.

Dopamine is the neurotransmitter most closely linked to schizophrenia. Neuroscience researchers have successfully cloned, sequenced, identified, and localized five different receptors for dopamine and now have demonstrated that one of these—the D4 receptor—is elevated in specific brain regions in schizophrenia. A further link

in this chain is forged by the findings that both clozapine and risperidone, recently introduced second-generation antipsychotic drugs which appear to have particular efficacy against the "negative" symptoms of schizophrenia, are particularly active in blocking this D4 receptor site.

Clinical research shows that these new antipsychotic medications enhance the accessibility of once-intractable patients to community-based treatments. Complementary research on medication efficacy are new services research studies on treatment effectiveness. For example, the NIMH-funded "Assertive Community Treatment" model, a managed care approach to providing severely disabled patients with intensive outpatient treatment, has demonstrated new models of treatment can be effective and at the same time substantially reduce treatment costs.

These findings from our schizophrenia research program represent a small part of our ongoing efforts recommended by the National Plan for Research in Schizophrenia and by the Decade of the Brain report. Similar illustrations of research efforts exist for other serious mental illnesses, including mood disorders, anxiety disorders, eating disorders, disorders of childhood, and obsessive-compulsive disorder. Rather than catalog these advances, I would like to describe briefly our efforts in other priority areas.

Mental health services research is a high NIMH priority, given the urgent need for reliable data about the effectiveness and cost-effectiveness of treatments for mental disorders in a variety of mental health service systems. This year, our investment in services research will reach 15 percent of our appropriated funds. We anticipate that this research will help inform discussions of mental health services and benefits as we reform our system of health care.

Research on child and adolescent mental disorders are also an NIMH priority. While much scientific effort is being directed at the severe disorders experienced by children, our research also is concerned with the causes, treatment, and prevention of childhood behavior problems. A recent contribution of NIMH researchers has been the utilization of sophisticated behavioral tests that can be administered to infants as young as six months who suffer from the genetic disorder phenylketonuria [PKU]. Though the disorder can be treated by dietary restriction of phenylalanine, the NIMH research has shown that even the "acceptable" level of phenylalanine in blood may cause significant cognitive deficits, and suggests that blood level guidelines should be reassessed.

In conjunction with the Board of Scientific Counselors of the NIMH Intramural Research Program, we are conducting an in-depth evaluation of that program. Our aim is to ensure that the Intramural program makes optimal use of the funding it receives and retains its reputation for innovation and leadership earned over the past 45 years.

Our budget reflects a unique convergence of public health needs, basic scientific data, and evolving clinical insights. To continue the scientific research activities highlighted here, and others, we request \$545,223,000.

I will be pleased to answer any questions.

BIOGRAPHICAL SKETCH OF DR. REX WILLIAM COWDRY

Education: 1968, A.B.—Yale College, (Psychology); 1973, M.D.—Harvard Medical School; 1973, M.P.H.—Harvard School of Public Health.

Licensed to practice Medicine, District of Columbia (1978–present), Commonwealth of Virginia (1977–present).

Professional experience: 1973–76, Resident in Psychiatry, Massachusetts Mental Health Center, Boston; 1975–76, Consultant, Washingtonian Center for the Addictions, Boston; 1977–78, Consultant, Mount Vernon Center for Community Mental Health, Alexandria, VA; 1977–81, Personal Psychoanalysis; 1977–present, Private practice (part-time); 1978–present, Department of Psychiatry, Georgetown University School of Medicine, Assistant Professor of Psychiatry (1978–79), Assistant Clinical Professor of Psychiatry (1979–83), Associate Clinical Professor of Psychiatry (1983–present); 1976–present, Intramural Research Program, National Institute of Mental Health [NIMH], Staff Psychiatrist (1976–82), Chief, Outpatient Depression Studies (1978–81), Chief, Borderline Personality Disorders Study (1982–87), Associate Clinical Director for Outpatient Studies (1982–83), Clinical Director (1984–87); 1984–87, Medical Board, The Warren Grant Magnusen Clinical Center, NIH, Chairman, Budget Committee (1985–86), Chairman of the Medical Board (1986–87); 1986–88, Acting Deputy Director, NIMH; 1987–present, Chief Executive Officer, Neuropsychiatric Research Hospital, Intramural Research Program, NIMH; 1994–present, Acting Deputy Director, NIMH.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you, Dr. Cowdry. Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RURAL MENTAL HEALTH RESEARCH

Question. The NIMH has recently established a Special Office of Rural Mental Health. To what extent do the mental health problems of our Nation's rural residents differ from those of city dwellers?

Answer. Available evidence suggests that rural Americans experience severe mental illness at about the same rate as the rest of the population: 15 percent during any six month period. However, there are fewer mental health professionals (as well as other medical professionals) available in rural areas to provide services. Two recently published reports from NIMH-funded research have refined this information and noted some important differences in mental disorders and service needs between rural and nonrural areas.

—One study found that rural Americans are no more likely to suffer from a psychiatric disorder than their urban counterparts, but their disorders were more likely to be "pure" than comorbid, i.e., having 3 or more psychiatric diagnoses at the same time. If this result is confirmed, it has important implications for the provision of services to the rural mentally ill.

—Another study in Colorado has made provisional conclusions regarding the need for services in that state (as defined by three measures of mental health status). The researchers found that rural towns showed the same level of needs as urban areas, but there was considerably lesser need in rural areas outside of towns. Urban areas showed the highest relative need for services and suburban areas manifested the lowest need rates in the state.

Question. Please detail for this Committee your Institute's research portfolio for fiscal year 1995 in the area of rural and native American mental health.

Answer. In fiscal year 1993, the last fiscal year for which NIMH has actual obligations, the Institute funded \$17.4 million for the support of rural mental health research. Six of the rural projects also qualified as native American research for approximately \$2.6 million. A further \$2 million of research was funded in native American populations that were not considered rural. In fiscal year 1994, NIMH expects to support \$18.6 million of rural mental health research and \$4.8 million of native American research, some of which also qualifies as rural research, as in fiscal year 1993. Although the Institute has not yet received grant applications for fiscal year 1995 funding, NIMH expects to commit \$19.6 million to rural mental health research and \$5.1 million for mental health research in native American populations. A comparable amount of the native American research will be in rural populations.

NIMH will continue to give priority to research on rural mental health issues in fiscal year 1995. NIMH has previously supported research on rural problems through a special announcement and funding of three rural research centers. There are also two additional centers with a primary focus on services research in rural populations, and one other center studying prevention of mental disorders in vulnerable rural youth. NIMH is supporting a contract to produce a report on the current state of Mental Health and Rural America: 1980–93. This report, in press, will guide potential rural researchers toward high priority topics. The report documents that one of the serious difficulties in meeting mental health problems in rural America continues to be the lack of qualified mental health service providers.

INSTITUTE OF MEDICINE REPORT

Question. What is the response from the National Institute of Mental Health regarding the 1994 Institute of Medicine report entitled, "Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research"?

Answer. The IOM Report, which is approximately 600 pages in length, was received by the NIMH only in the past few weeks and must be studied carefully.

The report is the product of a 2-year study, funded through a contract with the IOM by the NIMH and five other PHS components.

The tasks of the IOM, in developing the report, were to: Review the status of current research on the prevention of mental illness and problem behaviors; review the existing Federal presence in this area; provide recommendations on Federal policies and programs of research support leading to a prevention research agenda; render a "capacity building plan" to ensure an adequate supply of prevention researchers; and provide an estimate of resources (funding, manpower, etc.) needed for the future.

Question. Could you share any comments NIMH has at this time in response to the IOM report?

Answer. The IOM report appears to be a very thorough and scholarly analysis of the prevention research field. It addresses, in depth, a number of very important issues that the NIMH must carefully review. Some preliminary observations:

- The committee strongly recommends an enhanced research agenda to prevent mental disorders be initiated and supported across all relevant Federal agencies, including, but not limited to, the Departments of Health and Human Services, Education, Justice, Labor, Defense, and Housing and Urban Development, as well as state governments, universities, and private foundations.
- The agenda should facilitate development in three major areas: infrastructure building, knowledge base expansion, and preventive interventions.
- Based on an estimate of \$20 million for fiscal year 1993 for the Federal Government's expenditure for rigorous "preventive intervention research specifically targeted toward the prevention of initial onset of mental disorders," the IOM report recommends a five-year funding plan for Prevention Intervention Research that would support an additional \$20 million over the fiscal year 1993 level in years 1, 2, and 3, plus \$25 million in years 4 and 5.
- In addition, the IOM recommends that support for new specialized prevention research centers should start at \$2 million per year for 2 years, go to \$5 million in year 3, and then \$8 million per year in years 4 and 5.

Question. Could you make available to this committee the NIMH Council's formal response to this report?

Answer. NIMH would be happy to provide the Advisory Council's reaction to the IOM report as soon as it is available.

QUESTIONS SUBMITTED BY SENATOR DOMENICI

EQUITABLE INSURANCE COVERAGE FOR SEVERE MENTAL ILLNESSES

At this Committee's request, the National Advisory Mental Health Council authored a report on the need for health insurance coverage for individuals suffering from severe mental disorders. That report was released last year in a press conference with Senators Domenici and Simon, and has recently been reprinted in the *American Journal of Psychiatry*.

Question. In your professional judgment, do we now have a sound enough scientific basis to proceed with equitable coverage for individuals with severe mental illness, as described in Senate Report 102-397?

Answer. The report, *Health Care Reform for Americans With Severe Mental Illnesses*, asserts that insurance companies should set reimbursement rates for severe mental illnesses that are commensurate with those available for physical disorders. The division of diseases into medical and mental types becomes more arbitrary with every new study showing evidence of central nervous system pathophysiology in mental disorders. Just like physical diseases, mental disorders have been proven to have a biological basis and evidence suggests that genetic predisposition is a contributing factor. Like physical illnesses, mental disorders are diagnosable, treatable, and sometimes preventable.

Evidence from both clinical and basic neurosciences strongly suggests specific brain abnormalities in people with mental disorders. Such evidence comes from many levels, including, but not limited to, structural and functional brain abnormalities, as well as abnormalities in the way individual nerve cells communicate. New non-invasive technologies, such as PET (Positron Emission Tomography), SPECT (Single-Photon Emission Computed Tomography), and CAT (Computerized Axial Tomography) scans, have been successful in demonstrating biological changes in patients. Other lines of evidence for a biological basis of psychopathology include genetic linkage studies in families with a particular pattern of disorders and twin studies that have demonstrated a biological basis for schizophrenia.

The report also makes clear that for people with severe mental disorders, the chances of obtaining significant benefit through treatment have never been better. Unknown by many outside the field is the fact that a growing body of research

knowledge from clinical trials has verified the efficacy of these treatments for specific disorders, and has provided a useful scientific basis for clinical decisionmaking. Indeed, of the available treatments for mental illnesses, the majority are supported by extensive controlled clinical trials. Furthermore, the efficacy of many treatments for severe mental disorders is comparable to that in other branches of medicine, including surgery. The 6-month success rates for angioplasty and atherectomy—which are routinely covered by most insurance policies—are well below the rates for early response to treatments for most severe mental illnesses. This evidence set forth in the Advisory Council's report, then, makes continued discrimination in the way severely mentally ill individuals are covered by health insurance economically unwise and socially unreasonable.

Question. In other words, do we now believe that successful treatments can be provided for severe mental illnesses on a cost-effective basis?

Answer. The report makes clear that equitable coverage for severe mental illness would not only be cost effective, but also would most probably produce overall economic savings. Like many physical diseases, such as cardiovascular disorders, mental disorders affect large portions of the population, are disabling, and are effectively treated with medications and psychosocial interventions. The advisability of insuring against the catastrophic costs associated with these conditions was well established in the report. The \$6.5 billion cost of increasing such coverage (about 10 percent of the total cost of \$67 billion for all mental disorders in 1990) would be more than offset by an estimated \$8.7 billion reduction in other medical, social service, and other indirect economic costs incurred when these disorders are inadequately treated, according to the report.

NATIONAL CENTER FOR HUMAN GENOME RESEARCH

STATEMENT OF FRANCIS COLLINS, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Collins, Director of the National Center for Human Genome Research. Dr. Collins.

Dr. COLLINS. You have heard a lot about genes already today, from the others at the table. I will try to keep my comments very brief because of the time.

I appreciate very much your posing to this group the question that you have: What could we do with an investment of 50 percent more money? In the human genome project the answer to that is quite clear. Last fall, our program produced a detailed new 5-year plan which clearly outlines our priorities. You might ask, why did we do that, when we were only 3 years into the first 5-year plan.

The reason largely was because we had achieved a number of the goals that we originally thought were going to take 5 years in the mapping arena, and the technology has advanced rapidly enough that some of the other goals needed revision. So it was necessary to put forward a new and ambitious plan to outline what we will try to accomplish with the next 5 years' effort.

The area that we most need to invest in now, Senator, is DNA sequencing: To get all the A's, C's, G's, and T's that make up the blueprint of the human genome. We have done spectacularly well in the mapping arena and we had placed the highest priority on that in the early phases of this project. The biomedical research community was very anxious for these maps and the fact that these maps have produced results is reflected by all the excitement we heard about gene discoveries in the last year. Almost all of those gene discoveries were fed by the availability of genetic and physical maps that people needed to do the research. But because of financial limitations, we delayed investing in DNA sequencing technology and we really now have to make up for that.

The advisors on our 5-year plan looked at this situation and said we should immediately invest \$100 million a year in sequencing technology if we are going to take advantage of the opportunities that now exist and get this project done by the year 2005. This date is the original goal, and one which I do not wish to retreat from if I can possibly avoid it.

COMPLETION DATE

Senator HARKIN. I want to move it up. You can move it up, right?

Dr. COLLINS. When you asked this question last year we responded that, yes, we thought we could move the completion date up, perhaps by 3 or 4 years. I can come to you this year with great-

er confidence and say I am sure we can complete the human genome project 3 or 4 years earlier.

Senator HARKIN. With the \$100 million or more than that? You need more than that?

Dr. COLLINS. I think it would take more than \$100 million. We submitted an estimate last fall of what would be required to move the project up by about 5 years. We could revise that goal now, but it would end up inflating the total cost of the human genome project by about 50 percent. This is because we would end up doing the sequencing at a higher cost per base if we do it now instead of later.

But advances are occurring in DNA sequencing technology, particularly right now in miniaturization. Ideas that will allow you to do DNA sequencing on a credit card are extremely exciting, and those are coming along very rapidly. We are now in the position of being able to stimulate that field if we had resources to do so.

SUCCESS RATES

The current success rate in the National Center for Human Genome Research for our extramural grantees is 17 percent. In fiscal year 1995 with the President's budget, we estimate it will be 15 percent. So here we have this incredible research opportunity and we have recruited all these talented investigators, but we are not able to fund them.

Senator HARKIN. How come you are so much lower than the rest of them?

Dr. COLLINS. Part of that is the genome project is a growing field, so the number of investigators who want to work in this area is expanding because people are so excited about the potential. But our extramural budget has been effectively flat for the last 4 years. In contrast, we have benefited from an increase for the intramural program, which was also judged to be essential for science on the NIH campus, and for that we are very grateful.

But the extramural effort has not been able to ramp up to the level that the original budget plan submitted to the Congress 3 years ago recommended was needed. So we are living with this shortfall and eventually that will have consequences. Both the intramural and extramural programs are important. It would be devastating to sacrifice one for the other.

So I welcome your questions about additional resources. We could certainly come up with effective ways of utilizing them.

If I could, I would also like to comment on the FTE issue, because I think, as has been pointed out by some of the other Institutes that have not been around very long, FTE reductions are particularly painful for the new kids on the block.

I was fortunate to be given a mandate to start a new intramural program on the NIH campus, about which I am very excited. It was said that you cannot recruit good senior scientists to the NIH from the outside. Many of the Institute directors have also suggested that recruiting is very difficult because of Government constraints.

But because there was such excitement and such enthusiasm for the program, and because we had the ability to bring together a cadre of people who really like to work together, it was possible to recruit no less than 12 world-class geneticists to come to the NIH

campus. Some of these scientists left positions in the Howard Hughes Medical Institute, and some left endowed professorships that paid much more than what they are now getting as Government employees. But they chose to come together to do this very important and exciting research.

PREPARED STATEMENT

And now they are faced with this unexpected limitation upon FTE's which prevents them from being able to fully staff up their laboratories and recruit other individuals. It is very hard to live under those circumstances when you are just getting started. It is one of our greatest problems.

[The statement follows:]

STATEMENT OF DR. FRANCIS COLLINS

Mr. Chairman, this is the second time I have testified before this committee as Director of the National Center for Human Genome Research, a dynamic, four-year-old research program that in its short life has made unparalleled contributions to our understanding of human disease. My first year at the helm of this organization has been both challenging and rewarding, and I look forward with tremendous enthusiasm to the many opportunities that lie ahead for the Human Genome Project to make an even greater impact on genetic disease research.

The Human Genome Project has been so fast-paced and successful, NCHGR and the Department of Energy's human genome program have reviewed and extended the first set of 5-year goals established by those agencies in fiscal year 1991. The new set of goals covering years 4 through 8, and published in Science magazine, incorporate new technological developments into the research plan, keeping it ambitious and on the cutting edge.

This past year, the number of disease genes discovered using genome technologies was nearly four times that of the year before. Discovery of one of those genes, for a common form of inherited colon cancer, now makes it potentially possible to identify individuals predisposed to this often lethal cancer. Because colon cancer is often completely curable when it is detected early, this represents a prime example of how a gene discovery can lead directly to life-saving interventions. This gene was isolated within six months of when it was located on chromosome 2; in the past, such work would have taken several years.

Continued improvements in gene mapping technologies are likely to spur even greater increases in the rate of gene discovery in fiscal year 1995 and beyond. Genetic maps consist of markers along the chromosome, which let gene hunters know the area their gene is in. The first 5-year goal for genetic mapping has largely been met, and these maps have already played a central role in the search for disease genes. Under the new set of goals for genetic mapping, researchers will now improve upon those maps by developing markers that give better information and are even easier to use.

Once a gene has been located on a chromosome, the next step is to isolate it. Advances in physical mapping, that is, ordering pieces of DNA cloned from chromosomes, are also accelerating as the research groups set up a few years ago move into full-production mode. NCHGR now supports detailed physical mapping efforts on 10 of the 24 human chromosomes and 1 project to assemble a low-resolution map of the entire genome. Our colleagues at Genethon in Paris, partly supported by NCHGR, have also assembled an initial low-resolution physical map of the human genome. Other physical mapping efforts are expected to produce detailed maps of chromosomes 4, 7, X, and 22 by fiscal year 1995. Maps of chromosomes 3, 5, 12, and 13 will be near completion in 1995.

As success in one area always opens the door to new challenges in other areas, the Human Genome Project is beginning to focus its resources intensively on the next technological hurdle: DNA sequencing. Sequencing is the process of determining the order of the chemical subunits of DNA, known as bases. Understanding the order of bases in a DNA molecule is important because the order "spells out" genetic instructions for the cell. Alterations or mutations in the sequence of DNA bases are often the cause of disease. Understanding gene function will require cost-effective sequencing tools that can efficiently examine the anatomy of the various parts of

a gene and compare the structures of large regions of DNA between individuals or between humans and model organisms.

Technology development in DNA sequencing has so far focused largely on work in model organisms, such as the bacterium *E. coli* and the roundworm *C. elegans*, because their genomes are small and densely packed with genetic information. A collaboration between NCHGR-supported investigators in St. Louis and a research team in Cambridge, England, has resulted in an important milestone in DNA sequencing: each of these teams has produced 1 million base pairs of DNA sequence from that organism in a single year. The teams plan to increase their sequencing capacity by 5 fold this year. In this aggressive project, researchers are working to maximize state-of-the-art DNA sequencing technology while identifying new areas of development and refinement. NCHGR is also supporting efforts to improve sequencing efficiency by automating several steps in the sequencing process and by investing in radically new technologies for DNA sequencing.

As the maps of the human genome become more complete and more detailed, systematic methods for locating genes and placing them on the maps are needed. One of the goals in the new 5-year plan explicitly addresses this need. We will rigorously support the development of biochemical and computerized methods for identifying DNA regions that encode proteins. Rather than using current gene-by-gene approaches to identifying genes, these new methods should make it possible to identify all the genes in large regions of DNA. Such a large-scale gene-finding technique, known as "exon trapping," finally captured the renegade Huntington's disease gene last year by determining which of the DNA regions on chromosome 4 contained genes and which ones did not. Further research is needed to automate these techniques and make them more efficient for even larger regions of DNA.

The pace of successes in genome research makes it now more imperative than ever that we aggressively develop policy options for the ethical use of these technologies both within and outside the medical setting. Problems of how best to use the medical spin-offs of genome research are becoming more acute as genes for common illnesses are discovered. The gene for hereditary non-polyposis colon cancer discovered a few months ago, for example, is carried by an estimated 1 in 200 Americans. A test to identify individuals predisposed to this illness is imminent. Despite the potential of this test for saving countless lives, neither health care professionals nor the public is prepared to use or understand the implications of the test. The imminent discovery of a gene for hereditary breast cancer will add another example to this conundrum. In view of this situation, the National Advisory Council for Human Genome Research published a statement in the *Journal of the American Medical Association* recommending that genetic testing for predisposition to certain cancers be delayed until we gain more knowledge about how to deliver these tests in a way that will ensure the best health outcome and that is socially and psychologically responsible. NCHGR's Ethical, Legal, and Social Implications (ELSI) Branch has launched a new study that will give us important information to guide us in making policy recommendations about these issues.

The ELSI branch has already contributed a number of important documents to policy discussion. The NIH-DOE Task Force on Genetic Information and Insurance has examined the issues surrounding health insurance coverage for individuals and families with genetic health risks. The task force has made recommendations about how genetic information should be handled in a universal coverage system and has forwarded those recommendations to the White House Task Force on Health Care Reform. The ELSI branch also funded a study released last year by the National Academy of Sciences/Institute of Medicine Panel on Assessing Genetic Risks. This report offers recommendations for the regulation of genetic diagnostics laboratories, standards for how genetic services should be delivered, and for policies governing the use of genetic information by public health authorities. In addition, the ELSI program collaborated with the NIH Office of Protection from Research Risks in developing a new set of guidelines to protect the privacy of individuals and their families who volunteer for genetic research.

Finally, the newest NCHGR component, the Division of Intramural Research, is rapidly coming on line as a premiere medical genetics research program. Based at the NIH, with its unique ability to translate basic science into clinical advances, this laboratory will serve as a centerpiece for research in human genetics and molecular medicine throughout the NIH. The intramural division will focus on applications of genome science to the problems of human disease. This includes genetic contributions to cancer development, the development of tools to diagnose susceptibility to genetic disorders, and new strategies for gene therapy. In addition, the division's Medical Genetics Branch will provide a home for a dynamic training program in clinical genetics and genetic counseling.

As genetic technologies make their way into mainstream medicine at an ever increasing pace, the importance of public understanding of these technologies is paramount. In this new age of molecular medicine, many Americans lack the necessary understanding of DNA, genes, mutations, and inheritance to make informed decisions with their doctors about their health care. To ensure that citizens gain the most benefit from the new technologies spinning off from the Human Genome Project, NCHGR will be increasing its educational efforts to prepare the public to better handle these issues.

Mr. Chairman, the budget request for the National Center for Human Genome Research for fiscal year 1995 is \$152,010,000. I will be happy to answer your questions.

BIOGRAPHICAL SKETCH OF DR. FRANCIS S. COLLINS

Born: April 14, 1950, Staunton, Virginia.

Education: University of Virginia, 1970—B.S. (with Highest Honors); Yale University, 1972—M.S.; Yale University, 1974—Ph.D.; University of North Carolina School of Medicine, 1977—M.D. (with Honors).

Professional History: 1976–77, Fellow in Genetics and Biochemistry, University of North Carolina School of Medicine, Chapel Hill, North Carolina; 1977–78, Intern in Medicine, North Carolina Memorial Hospital, Chapel Hill, North Carolina; 1978–80, Assistant Resident in Medicine, North Carolina Memorial Hospital, Chapel Hill, North Carolina; 1980–81, Chief Resident in Medicine, North Carolina Memorial Hospital, Chapel Hill, North Carolina; 1981–84, Fellow in Human Genetics and Pediatrics, Yale University School of Medicine, New Haven, Connecticut; 1984–88, Assistant Professor of Internal Medicine and Human Genetics, University of Michigan Medical School, Ann Arbor, Michigan; 1987–88, Assistant Investigator, Howard Hughes Medical Institute, Ann Arbor, Michigan; 1987–91, Chief, Division of Medical Genetics, Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, Michigan; 1988–91, Associate Professor of Internal Medicine and Human Genetics, University of Michigan School of Medicine, Ann Arbor, Michigan; 1988–91, Associate Investigator, Howard Hughes Medical Institute, Ann Arbor, Michigan; 1991–93, Professor of Internal Medicine and Human Genetics, University of Michigan School of Medicine, Ann Arbor, Michigan; 1991–93, Investigator, Howard Hughes Medical Institute, Ann Arbor, Michigan; 1993 to present, Director, National Center for Human Genome Research, NIH, Bethesda, Maryland.

Board Certification: Board of Medical Examiners, State of North Carolina, 1977; American Board of Internal Medicine, 1980; Board of Medical Examiners, State of Connecticut, 1981; American Board of Medical Genetics, 1984; Board of Medical Examiners, State of Michigan, 1984.

Professional Organizations: American Association for the Advancement of Science; American Society of Human Genetics, Human Genome Committee, Ad Hoc Committee on Cystic Fibrosis Screening, Board of Directors; American Scientific Affiliation; American Federation for Clinical Research; American Society for Microbiology; American Society of Hematology; American Society for Clinical Investigation; Human Genome Organization [HUGO], Executive Council; Institute of Medicine.

FTE'S

Senator HARKIN. Everybody does come under this FTE's.

Dr. VARMUS. More than before. People who were above the ceiling before are now under the ceiling, so there has actually been a loss of exemptions.

Senator HARKIN. Exactly.

Dr. COLLINS. Scientists find it very hard to accept that people on Capitol Hill believe that they are administrators, but that is what they are basically being told: You are an FTE that is subject to administrative reductions. And here they are working at the laboratory bench. It is a strange definition as it applies to science.

Senator HARKIN. I have a hard time about doing some kind of an exemption. I am trying to think of some way of doing it. We may be able to figure something out.

I am sorry, I did not mean to keep interrupting. Do you have anything else, Dr. Collins?

INTRAMURAL INCREASE

Dr. COLLINS. If I could take 1 more minute. I am constantly being asked: What is the story on the intramural program, what is this going to contribute to the NIH, why is it necessary to have it funded to ramp up over only 2 years?

If I could give an analogy about this, it might perhaps clarify things a little bit. I think you can think of the field of genetic medicine, one of the most exciting things that is going on right now, as a hospital. If you are going to run a hospital, you have to build the building. You have to have the infrastructure. You have to have walls and bricks and mortar and paint and computer lines and electricity.

What the extramural genome project is providing to genetic medicine is that infrastructure, the maps and the DNA sequence. But if you are going to run a hospital, you need people in there applying all of their skills and creativity to the problems at hand. That is the business of the entire biomedical research community as applied to genetic medicine. So we are making that possible by building the necessary infrastructure through the extramural program.

If you will allow me to press this analogy just a little further, I think of the NIH intramural program up there in Bethesda as a centerpiece of biomedical research, the main operating room, if you will, of this very important hospital. But it is an operating room which, in order to function at maximum efficiency and to be most successful, has a lot of high tech instruments that somebody needs to know how to run. Somebody needs to be there twiddling the dials working with the heart-lung machine, the anesthesia machine, the scanners, all the gadgets that an operating room of this sort needs.

That is in effect what we are trying to do with the intramural genome program: To provide that high technology capacity for the main operating room of genetic medicine, in order to make the place really hum. That is what it is all about.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Very good. I kind of like that analogy. Thanks, Dr. Collins.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HUMAN GENOME RESEARCH COLLABORATIONS

Question. It's my understanding that the Human Genome Project involves the work of a variety of sources, both at the NIH and outside it.

Please describe the division of labor between the Genome Center's intramural and extramural programs, between the Genome Centers and the gene therapy research conducted at other NIH Institutes, and between the NIH and the Department of Energy. Also, what's the breakdown of funding between NIH and DOE?

Answer. The National Center for Human Genome Research's [NCHGR] extramural program is a well established, vital program whose mission is to analyze the structure of human DNA and determine the location of the estimated 100,000 human genes. The support of this basic research has resulted in the development of a rich diversity of new research tools. These tools will have tremendous benefits for biomedical research and have already made important contributions to a variety of research projects. For example, the pace of gene discovery has increased substantially because of the research tools developed by the Human Genome Project. These discoveries can be expected to result in extraordinary medical benefits from our ability to understand the genetic factors of health and disease. In addition, the Human Genome Project has created the Ethical, Legal, and Social Implications Branch to define the challenging issues related to the generation of human genetic information and to develop initial policy options to address them.

The intramural program has an entirely different, but complementary, mission. This program was established in February 1993 to serve as a central hub for the NIH where the development of technology for the rapid isolation and analysis of disease genes will be carried out, together with research on genetic diagnosis and gene therapy. Research will include identifying and understanding the molecular basis of human genetic disease and planning and conducting clinical trials to test methods for the treatment, and perhaps the cure, of genetic diseases.

The intramural program of the NCHGR has been established as the focal point for collaborations with other human genetics research efforts at the NIH, complementing ongoing activities in human molecular genetics, structural biology, and gene therapy. Gene therapy is a key initiative and component of a number of NIH Institutes. Scientists in both the intramural and extramural programs have made significant progress in the identification of the genes responsible for many hereditary diseases. Identifying the genes responsible for a given disease is a critical first step in the initiation of gene therapy. The NCHGR has already established very effective liaisons with a number of other Institutes at the NIH to maximize the strengths of existing programs and provide a state-of-the-art genetic research focus for the NIH.

With regard to the Department of Energy, the NCHGR has long-standing and very effective coordination with this agency's genome program. The two agencies have jointly developed and issued two long range plans for the Human Genome Project. The agencies continue to collaborate formally through the standing joint committee of members of the NIH's National Advisory Council for Human Genome Research and the DOE's Health and Environmental Research Advisory Committee, as well as through numerous, effective informal collaborations. In particular, the collaborations between the two agencies with regard to the ethical, legal, and social implications of genome research are highly effective. They have resulted in the analysis and study of a number of seminal issues in this field, as well as the publication of key documents, including "Genetic Information and Health Insurance," a report of a Task Force of the NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research.

The budget for NIH and DOE (excluding the Division of Intramural Research) is:

THE BUDGET FOR THE HUMAN GENOME PROJECT

[In millions of dollars]

	1990 actual	1991 actual	1992 actual	1993 actual	1994 estimate	1995 request
National Institute of Health	59.5	87.4	104.8	106.1	107.7	112.6
Department of Energy ¹	27.2	47.4	61.4	64.5	68.0	73.9
Total	86.7	134.8	166.2	170.6	175.7	186.5

¹ DOE figures do not include salaries and expenses of DOE employees devoted to this effort

PROGRESS OF MAPPING AND SEQUENCING

Question. You have stated that some aspects of the Genome Project are ahead of schedule, but others are falling behind. Please review the progress made so far in mapping and sequencing, and how the rate of progress will affect the Project's ability to attain its 15-year goals?

Answer. Progress on the Human Genome Project has been remarkably rapid and the project is currently on schedule. Great strides have been made toward the achievement of the initial mapping goals thanks, in part, to advances in technology. A first-generation genetic map is essentially complete, nearly two years ahead of the

expected completion date. The improved quality of this map has reduced the time required to map a gene from a period of years to a matter of months in many cases. However, the map is still far from ideal, so efforts have turned toward improvements that will make the map more useful and accessible. It is hoped that continued improvements in the human genetic map will reduce the time required to map a gene to a matter of weeks.

Progress has also been very rapid on the other major type of genomic map being developed, the physical map. A physical map of the human genome, with some regions mapped in more detail than others, is expected to be available in the next two to three years and a highly detailed map is expected within five years.

These advances have been achieved by focusing the effort on mapping as the essential early phase of the Human Genome Project. As the budget for the U.S. program has not reached the level originally called for by the NIH-DOE advisors, this has meant that relatively less has been invested in the area of DNA sequencing during this period. This is not to say that steady significant progress has not been made in technology development for DNA sequencing. At the start of the Human Genome Project, the longest contiguous stretch of DNA that had been sequenced was the 250,000 base pair sequence of cytomegalovirus. Last month, a U.S.-U.K. collaborative team announced the sequencing of a 2.2 million base pair region of DNA, approximately a ten-fold increase in sequencing capability.

However, in spite of such progress, the current rate of advance in sequencing technology is far from sufficient to be confident that the complete sequencing of human DNA will be finished by the year 2005 at the originally projected cost. Although the goal of sequencing DNA at a cost of \$0.50 per base pair may be met by 1995, or soon thereafter, the rate at which DNA can be sequenced currently will not be sufficient for sequencing the whole human genome. Overall sequencing capacity will have to double annually for at least the next 8 years if that task is to be successfully completed by 2005. Achieving this rate of increase will be a formidable task that will require a greatly enhanced technology development effort, as well as a larger number of research groups working in this area. Therefore, additional investment in new sequencing technologies is of the very highest priority.

ALLOCATION OF EXTRAMURAL AND INTRAMURAL ELSI BUDGET

Question. The fiscal year 1995 budget for the Genome Center includes \$5.3 million for extramural support of research to study the ethical, legal, and social issues arising from human genome research. Could you describe how this money will be allocated and how and who will conduct this research? Will the intramural program be involved in similar studies?

Answer. As you indicate, 5 percent of the NCHGR budget (both extramural and intramural) is set aside for ethical, legal, and social implications [ELSI] research by law. The ELSI Branch in the Division of Extramural Research supports investigator-initiated research projects designed to examine issues surrounding the use of genetic technologies resulting from the Human Genome Project. This research is carried out by investigators located at research institutions and related facilities all around the United States.

The extramural ELSI program is currently funding projects designed to develop the conceptual and theoretical framework and establish the underlying body of knowledge needed, in order to develop sound policy options and recommendations in the area of human genetics and genome science. Examples of research currently being funded are projects which are examining the impact of the use of genetic technologies in diverse populations, determining factors that influence the diffusion of genetic tests especially in primary care settings, identifying ethical issues faced by physicians, nurses and other health professionals as the use of genetic technologies expands, examining communication patterns between health care providers and women considering reproductive genetic testing. Additionally, ELSI is funding projects designed to develop model education programs for health professionals as well as the general public about ethical, legal, and social issues which surround the Human Genome Project.

This year the ELSI Branch undertook a new initiative (in conjunction with the National Cancer Institute, the National Institute of Nursing Research, and the National Institute of Mental Health) entitled, "Genetic Testing and Counseling for Heritable Breast, Ovarian and Colon Cancer Risks." This initiative is designed to examine the psychosocial and clinical impact of using gene-based diagnostic tests in families with heritable forms of breast, ovarian, and colon cancer, to identify those individuals who have an increased risk of developing cancer and those who do not; to assess public knowledge and attitudes about genetic testing for cancer risks; and

to gather information needed to establish clinical protocols for the optimum use of these risk assessment technologies in the future.

The NCHGR's intramural program is less than one year old and plans for the program are still developing. Nevertheless, in the past year an Education and Outreach Program has been established and is already gaining visibility and a national reputation. An ethics research program is also being developed.

In addition, members of the Medical Genetics Branch of the intramural program are directly involved in a variety of ELSI issues, including discussions with a number of professional societies about the optimum use of genetic testing to determine heritable cancer risks.

The ELSI activities in the extramural and intramural programs will be closely monitored to assure they are complementary and not overlapping. Overall planning and coordination is provided by the Ethical, Legal, and Social Implications Working Group.

QUESTION SUBMITTED BY SENATOR BOND

CAUSES AND CURES FOR BIRTH DEFECTS

Question. One area that I have spent a great deal of effort is in the prevention of birth defects. That work has centered on public/private efforts to study the causes of infant mortality and birth defects and to find cures or treatment for birth defects when possible * * *. At the National Center for Human Genome Research, what are the implications of this important work to find the causes and cures for birth defects? What are the prospects for treatments and tests and what are the ethical considerations for this research?

Answer. Birth defects are the leading cause of infant mortality in the United States. Many birth defects are known to be associated with genetic factors. The National Center for Human Genome Research's investigations are contributing to a better understanding of the genetic causes of and treatments for birth defects. In addition, technologic advances associated with the Human Genome Project are aiding in determining factors which result in genetic susceptibilities to environmental causes of birth defects. Perhaps most importantly, however, these breakthroughs are resulting in a better understanding of the genetic contributions to normal development, including both structure and function.

Molecular genetic approaches offer the potential for the early identification of children born with birth defects, many of whom may benefit from a variety of prevention or intervention strategies. Molecular genetic technologies are already being used to produce biological substances which are altered or missing in some children born with birth defect problems. Examples include the production of such substances as human growth hormone which is used in the treatment of short stature problems and factor VIII which is used in the treatment of hemophilia. Other exciting and more recent advances are those associated with the possibility of providing somatic (body) cell gene therapy for diseases such as adenosine deaminase deficiency, cystic fibrosis and some forms of cancer, which can occur in children.

It is imperative that ethical issues surrounding the use of these technologies in the diagnosis and treatment of birth defect problems in children continue to be examined. For example, it is important that parents understand the risks as well of the benefits of their children undergoing genetic testing. Alternative methods for treatment should be fully discussed with any parents considering the use of gene therapy in the treatment of their child's birth defect problem. It is also important that children's rights be protected and their privacy be maintained, so that any risk for untoward effects (e.g. discrimination or stigmatization) potentially associated with the use of these technologies be minimized.

NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DONALD LINDBERG, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Lindberg, Director of the National Library of Medicine.

Dr. LINDBERG. I will try to be very brief, Senator. It is a pleasure to be with you.

Were we to get a 50-percent increase in funding, it would have a beneficial effect extramurally and intramurally. We are now funding about 18 percent of grants and we would be able to raise that to about 40 percent.

I think intramurally it is important that we increase our funding and FTE levels so as to protect our basic library services and to respond to new program initiatives. We would increase our focus on ways in which biomedical research and practice can capitalize on this incredible progress in information systems. We are constantly reading in the papers about the electronic highway of the future and the importance of high-performance computing and communication programs. I currently am involved in coordinating the latter efforts throughout the government.

I do not want medicine to be left on the side of the highway. The Internet and the HPCC technologies are being used very effectively by chemists, physicists, and engineers. We want the health professionals and the inpatients to benefit as well.

To bring this about we are funding outreach grants and testbed network projects which link hospitals, medical schools, and libraries for health care delivery. Two of the leading States in this area are Iowa and North Carolina. They have made a commitment to developing statewide networks. So we would increase the funding for that kind of program and include what is called telemedicine, treating patients at a distance, and regional consortia which utilize automated information systems.

In closing, I want to emphasize that the programs that I am speaking about are jointly sponsored with other agencies, among them the Agency for Health Care Policy and Research, ARPA within DOD, the Indian Health Service, the VA, and the National Cancer Institute.

PREPARED STATEMENT

So we really would like to see a very broad base to those programs and we want to be sure that, as I say, medicine benefits from the electronic progress which has been so abundant.

But I thank you for the support in the past and the dreams of the 50-percent increase.

[The statement follows:]

STATEMENT OF DR. DONALD LINDBERG

Mr. Chairman and members of the committee, I am pleased to tell you that the National Library of Medicine has recently taken significant steps to open even further its vast holdings to the world. The Library's entire catalog listing of book, serial, and audiovisual holdings is now available over the Internet through a new system known as "NLM Locator." The Library levies no charge for this access.

Simultaneously, the NLM is encouraging U.S. medical institutions to gain access to the Internet. The Internet is the existing widely used high-speed communications network that is a prototype for the "Information Superhighway" of the future. To help ensure that the health professions are taking full advantage of information on the superhighway, the Library offers access grants to medical institutions. This program, offered by NLM in collaboration with the National Science Foundation, has proved to be very popular. It may be seen as a step toward the creation of a nationwide (and, ultimately, worldwide) electronic biomedical community. This work has been made possible because of funding the Congress earmarked for Outreach in the past and also because of new funds earmarked for NLM participation in the High Performance Computing and Communications [HPCC] initiative.

This committee has heard in the past about how the Library has extended access to its electronic databases to individuals—to doctors, scientists, other health professionals, and students. This emphasis on access for the individual continues. The community of enthusiastic database searchers supported by the Library, reported last year as 60,000, has risen to 82,000. Most of these are individuals who use the Library's Grateful Med software on a personal computer and thus have 24-hour access to MEDLINE and other NLM databases. In addition, of course, the 4,100 U.S. medical libraries are all institutional users of the same services, each handling the information needs of hundreds of physician and scientist users.

It is a pleasure to report that in 1994 the Library took a much-applauded step by opening up its four AIDS-related databases to all users on a completely cost-free basis. Along with this step, we are encouraging access by those who have not traditionally used our databases—patients and the general public. For example, a public library or a community-based health organization can receive a special code from NLM that will allow free access to the AIDS databases. This means that the library or organization can make a terminal available for unlimited searching by the general public. The databases covered include the extensive published literature on AIDS (journal articles, books, audiovisuals, meeting reports), and also the drugs being tested and clinical trials being conducted. This last includes a listing of clinical trials that are recruiting patients, complete with telephone numbers and other data to help a person or family member to get enrollment information. Another database lists the many organizations that provide information to the public about AIDS.

This opening up of the Library's databases to the public is a departure from past practice. Although the NLM never refused access to anyone, the emphasis was on outreach to health professionals and to the institutions that serve them. We hope to learn about how to serve the public more directly. Will many individuals take advantage of the free access? Will we do a good job? Will we do a good job with underserved populations? Last year some 6 million searches were done nationwide, almost solely by health and medical library professionals. It is estimated that an additional 15 million searches are done each year by those who use NLM databases on compact disk, or who use MEDLINE on commercial online database services, or who use NLM databases through the facilities of our partner organizations in 18 foreign countries.

Another innovation just announced by the Library is the creation of a database, "HSTAR," containing much information on subjects touching on health care reform. "HSTAR," which stands for Health Services Technology Assessment Research, is a database with 1.3 million records. HSTAR is unusual among NLM databases in that it contains references to government reports, books, book chapters, meeting abstracts, and, soon, newspaper articles, in addition to the selected pertinent references and abstracts from MEDLINE and several other NLM databases. The database was developed by the NLM in cooperation with the Agency for Health Care Policy and Research as part of the Library's recent mandate from the Congress to expand its information services in such areas as health services research methods, technology assessment, clinical practice guidelines, bioethical considerations, financing, evaluation, planning, and quality assurance. The emphasis is on the practical: "I can go elsewhere for theory, but I use HSTAR to gain expertise in practical applications such as state HMO plans * * *" one HSTAR user told us. The database even contains comparison data of various medical equipment and devices on the market—of great value to hospitals in keeping costs down while maintaining qual-

ity. The new database should be helpful to administrators, planners, policy makers, legislators, third-party payers, health service researchers, and the information specialists who serve these groups. HSTAR is available under the same conditions as MEDLINE and most of the other NLM databases, that is, at an average cost of about \$1.25 per search.

RESEARCH AND DEVELOPMENT

The multi-agency High Performance Computing and Communications [HPCC] initiative, a keystone of the American science and technology enterprise in the 1990's, has become an important part of the Library's program in both Research and Outreach. The Library components that are most affected initially are the Lister Hill National Center for Biomedical Communications and the National Center for Biotechnology Information. Increasingly, though, the National Network of Libraries of Medicine and the Library's Information Center on Health Services Research and Health Care Technology are becoming involved in electronic highway programs. The National Coordination Office for HPCC, headed by the NLM director, continues to reside at the Library.

A \$4.15-million contract, awarded at the end of fiscal year 1993, is supporting a consortium of West Virginia institutions to install a system that applies advanced networking technologies to delivering health care in both rural and urban areas of the state. The objective is to demonstrate that physicians can treat patients using electronic patient records and information from distributed sites, and that a network of primary care and specialized care providers can collaborate to meet community health needs.

In addition to the West Virginia project and the program of grant support to assist medical institutions to link up to the Internet, mentioned earlier, the NLM has just announced that it is funding 11 additional HPCC health-related applications that were submitted in response to our Broad Agency Announcement. They range from testbed networks (citywide, statewide, and national), to virtual reality experiments, to telemedicine (both statewide and discipline-based systems), to information access (linking images to patient records). The successful outcome of these projects will, we hope, help to contain health care costs through sharing scarce resources while raising the quality of patient care.

Another project in the HPCC arena is in the area of imaging. This is the "Visible Human" project that seeks to build an immense digital image library representing submillimeter x-y-z numerical coordinates of the male and female human body. The first phase, to acquire image data from photographic, computed tomography, and magnetic resonance imaging, is now under way, and the set of images resulting will be made available widely to the medical community over the Internet, probably later in 1994. This project promises to provide an unprecedented image resource for use in medical education and in developing computer graphics tools for computer-aided surgical planning.

NLM's National Center for Biotechnology Information in 1992 took over responsibility for the GenBank DNA Sequence Database. The Center has been successful in expanding the scope of the database and the forms in which it is available. Some 3 million searches a year are now being done on GenBank—both online and on compact disk. The Center's scientists also perform research into advanced methods of computer-based information processing for analyzing the structure and function of biologically important molecules and compounds. These methods are widely published and made available to scientists around the world. In summary, the National Library of Medicine is making its computerized information services available to an ever-widening audience, we are creating and making available new databases that respond to national needs, and by supporting High Performance Computing and Communications projects—both within the NLM and in the medical community at large, we are investing in future information systems and services. I would emphasize that we are doing all this while protecting the integrity of the Library's unparalleled collections, maintaining NLM's basic services to the medical library community, and serving on-site patrons at our facility in Bethesda.

Mr. Chairman, the fiscal year 1995 non-AIDS request for the National Library of Medicine is \$135,330,000. I shall be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. DONALD A.B. LINDBERG

Born September 21, 1933 and raised in New York City. He is married and the father of three sons.

He was graduated from Amherst College in 1954 with a degree (*magna cum laude*) in biology and accepted to the Columbia University College of Physicians and

Surgeons. He earned his doctor of medicine four years later from that institution. He is the recipient of Sc.D. degrees (hon. caus.) from Amherst College and from the State University of New York Health Science Center at Syracuse, and an LL.D. (hon. caus.) from the University of Missouri (Columbia). Among his academic honors are Phi Beta Kappa, Simpson Fellow of Amherst College, and Markle Scholar in Academic Medicine (1964-69).

After earning his M.D., Dr. Lindberg was an intern and later assistant resident in pathology at Columbia-Presbyterian Medical Center, an Assistant in Pathology at the Columbia University College of Physicians, and a resident physician in pathology at the University of Missouri School of Medicine. This last was the first in a series of positions of increasing responsibility at the University of Missouri: Director of the Diagnostic Microbiology Laboratory (1960-63), Instructor, Assistant, Professor, Associate Professor, and Professor of Pathology (1962-84), Director of the Missouri Regional Automated Electrocardiography System (1967-69), Director of the Medical Center Computer Program (1962-70), Director of the Regional Medical Program Information Systems (1967-70), Professor and Chairman, Department of Information Science, School of Library and Information Science (1969-71), Consultant for Health Sciences to the Vice President for Academic Affairs (1972-73), Director of the Health Services Research Center, and Director of the Information Science Group, School of Medicine (1971-84). In 1984, Dr. Lindberg was appointed Director of the National Library of Medicine. In 1988 he was appointed Adjunct Professor of Pathology at the University of Maryland School of Medicine and, in 1992, Clinical Professor of Pathology at the University of Virginia. In 1992, he was also appointed the first director of the National Coordination Office for High Performance Computing and Communications, a position concurrent with his directorship of the NLM.

Dr. Lindberg is a member of many professional organizations, among them: Sigma Xi; American Society of Clinical Pathologists; College of American Pathologists; American Association for the Advancement of Science; Association for Computing Machinery; American College of Medical Informatics (Board of Directors); Symposium on Computer Applications in Medical Care (Board of Directors); National Board of Medical Examiners (Board Member); National Academy of Practice in Medicine (Distinguished Practitioner); National Academy of Sciences—Computer Science and Engineering Board; Institute of Medicine—Board on Health Sciences Policy. He was a founding member and first President of the American Medical Informatics Association.

He is the author of four books and more than 150 articles, reports, and monograph chapters. In addition, he has served as editor of Information Methods in Medicine, Lecture Notes in Medical Informatics, and the Journal of Medical Systems.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. We are going to make that a reality. It is going to happen. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Library for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

TESTBED NETWORKS

Question. I understand that NLM is making several research contract awards for testbed networks which link hospitals, doctor's offices, medical schools and libraries for exchange of medical data. What do you think the importance of these projects is for the future of health care in our country?

Answer. The information that health care professionals need to provide the best service is voluminous, and far exceeds what an individual human being can possibly remember or use effectively to make decisions. Thus health care has become a communication-intensive team enterprise, requiring effective means of exchanging patient-specific data and access to the vast body of recorded knowledge in medicine found increasingly in computerized form. Information technologies appear to have the potential to make health care delivery more effective and as well as more efficient, but the effect of advanced information technologies needs to be critically and carefully evaluated and documented. We do not expect computing and networks to be a panacea, but do expect that they will have a useful and measurable impact in certain areas, such as diagnostic interpretation of clinical images and the reduc-

tion of unnecessary testing caused by lost or inaccessible paper-based records. The NLM's research contracts emphasize not only innovative information technology development and its application to medical applications, but the careful and rigorous measurement of its impact on health care delivery. The lessons learned, as well as the successful systems developed, will be the important building blocks for the future of the health care in our country.

TELEMEDICINE TECHNOLOGIES

Question. There's been some exciting recent developments in telemedicine technologies. What is NLM doing to advance these technologies?

Answer. A specific research focus of the HPCC Broad Agency Announcement was the creation and evaluation of telemedicine technologies for the collaborative treatment of patients by health care providers in different locations. Work being funded by the NLM via research contracts includes:

(1) A project which will use the newly developed state-wide digital network in Iowa for creation of a Telecommunications Health Education Resource Center, linking of three rural hospital sites, improved information services for rural health care providers, and several Telemedicine prototype systems.

(2) A project linking six outlying hospitals in western Pennsylvania with the University of Pittsburgh Medical Center for teleradiology to improve neurosurgery, neurology, trauma and critical care. The impact of the system on patient outcomes will be studied.

(3) Remote diagnosis of skin lesions via teleconsultation to underserved rural areas will be developed and tested in five primary care clinics in Oregon and Kansas.

(4) A consortium of nine institutions led by the Concurrent Engineering Research Center of the University of West Virginia will build and evaluate a regional telemedicine system for rural areas of the state.

An important component of each of the telemedicine projects is a careful evaluation of their impact on the process of health care delivery and on patient outcomes.

QUESTIONS SUBMITTED BY SENATOR COCHRAN

MISSISSIPPI HEALTH INFORMATION NETWORK

In my state of Mississippi, I know that many state agencies, health associations, and academic institutions, as well as private health care providers, have joined together to implement an electronic information exchange program that provides the latest health research information to the widest possible audience throughout our rural state. (this program is the Mississippi Health Information Network [MisHIN]).

Last year the Mississippi Health Information Network [MisHIN] was funded through the National Library of Medicine. The project received a \$1.1 million expansion grant for three years. (Fiscal year 1994—\$439,000, fiscal year 1995—\$290,000, fiscal year 1996—\$266,000).

I would like to take this opportunity to reaffirm my support for continued funding for the High Performance Computing Center which benefits Mississippi through the National Library of Medicine.

Additionally, I would like to express my support for continued funding for the National Library of Medicine. There are 2 hospitals in Mississippi which receive funding through the Lower Mississippi Delta Projects of the National Library of Medicine. A third hospital is in the developmental stage.

Question. Are you aware of the Mississippi Health Information Sciences Network?

Answer. We consider MisHIN to be one of our most important information resources projects, and have, as you know, awarded the project a three-year grant to encourage development of the system. MisHIN may well be the most ambitious, and potentially important of our Information System grants because of the enormous possibilities of networking academic and community health delivery units involving such a large variety of services and professionals, and with so wide a distribution across the state of Mississippi. The potential benefit to a large population, many of whom are underserved, may well serve as an important model for efforts elsewhere.

Question. Do I have your assurance that the remainder of the funds for fiscal year 1995 and fiscal year 1996 will be given?

Answer. MisHIN has an extremely high priority for NLM, and we have every expectation of being able to fulfill our obligations to the program for the remaining years of the grant. Even if grant funds are curtailed by government budget decisions we intend to use what funds we get to honor the needs of existing grants such as MisHIN before we fund any new applications.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY
IN THE HEALTH SCIENCES

STATEMENT OF PHILIP SCHAMBRA, Ph.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Schambra, Director of the Fogarty International Center.

Dr. SCHAMBRA. Thank you, Senator Harkin.

Senator, one of the four principal priorities of the Fogarty International Center which has come out very strongly in our recently completed long-range plan is that of mobilizing international research efforts against global health threats.

We are already very actively involved in this No. 1 priority through our AIDS international research and research training programs, largely in Africa and in Latin America, and in developing the human infrastructure with which AIDS vaccine field trials eventually will take place.

With a 50-percent increase in our overall budget, about 40 percent of this amount would be devoted to this effort by expanding our research and research training programs into the Far East and Western Pacific and areas where the AIDS epidemic is exploding—in India, in Thailand, in Burma, and other parts of that region.

We would also focus major efforts on other new and emerging infectious diseases. Dr. Fauci mentioned tuberculosis as being an example of a re-emerging disease. There are other examples. The recent re-emergence of the Hanta virus in the Four Corners area of the Southwest and other areas as well suggest that we can with certainty expect other emerging and re-emerging diseases to be coming along in the future.

In addition, working with the Child Health Institute, we would focus major attention on the problems of population growth and the impacts on global health. Working with the Environmental Health Institute, we would focus on environmental pollution and global climate change.

Dr. Olden mentioned the importance to his Institute of doing more in the way of human and population studies. Information that can be very useful in human and population research will come from studies that will take place abroad, in Eastern Europe for example, where the pollution levels are exceedingly high, and in China, where indoor air pollution is considerable from burning wood.

So these are where our priorities are, and I would be pleased to expand on them for the record. In addition, I will submit for the record our response to your question regarding the impact of FTE reductions.

[The information follows:]

FIFTY PERCENT INCREASE IN FUNDING

Following is further elaboration of the FIC priorities for use of a 50-percent increase in funding:

Emerging Infectious Diseases.—The potential threat of devastating new infectious disease underscores the need for international cooperation to identify new patterns of disease and modes of transmission. Cooperative research would be fostered with regions of the world where new infections are most likely to occur due to rapid social and ecological change and would pose health threats to the citizens of the U.S. and other nations. Research emphasis would be placed on the complex interactions between humans and microbes and on the evolutionary and genetic factors that cause epidemics.

Health and Population.—Unsustainable population growth presents perhaps the leading challenge for public health, the environment, and economic progress as we enter the next century. International partnerships would be fostered between U.S. universities and research institutions and counterparts in strategic regions of the world to include studies on reproductive health, determinants and consequences of population growth, demographic change and contraceptive development and evaluation.

Health and the Environment.—The potential adverse health effects resulting from exposure to environmental chemicals are often first identified in populations of other countries. Cooperative research would be fostered with regions of the world with relatively high contamination levels which present unique opportunities to study the effect of environmental agents on human health and to develop new interventions.

International Cooperative Biodiversity Groups.—The contraction of natural habitats—and in particular the destruction of species-rich tropical rain forests—will have profound economic, environmental and scientific consequences. The FIC would expand the interagency program to include additional developing countries with important indigenous biological resources.

Fogarty International Research Collaboration Awards.—In efforts to foster research partnerships between U.S. scientists and their counterparts in previously less accessible regions of the world, the FIC established the FIRCA program. The FIC would expand the program to include other regions of the world with early priority given to Africa and the Middle East.

International Research Training Opportunities for American Scientists.—Effective scientists are internationalists, capable of working and communicating across national borders. Toward this effort the FIC would provide opportunities for junior American postdoctoral scientists to conduct research abroad. Special emphasis would also be placed on expanding international opportunities for minorities underrepresented in the scientific professions by enabling minority undergraduate and graduate students and faculty to undertake coursework and independent research at centers of academic excellence abroad.

International Studies on Maternal and Pediatric HIV/AIDS.—Due to the high burden of maternal and pediatric HIV infection in other regions of the world, international cooperation on population-based studies will accelerate the development of prevention strategies to curtail the epidemic in women and children. Based on the recent encouraging findings of the effectiveness of Zidovudine in preventing vertical HIV transmission from HIV-infected mothers to their infants, there is a great global need to evaluate such interventions in developing countries, adapted to local situations that would facilitate use in developing countries, and to aggressively pursue other possible intervention strategies, such as the use of Vitamin A to prevent vertical transmission.

HIV/AIDS Intervention Studies.—We are expending considerable effort to develop the infrastructure for future international trials of candidate HIV/AIDS vaccines. These international sites in some 8 or more countries include populations at high risk for HIV infections, populations especially suitable to participation in studies of other non-vaccine interventions and who will potentially benefit from these studies. Currently it is proposed to utilize infrastructures established for the conduct of AIDS vaccine efficacy trials, in addition, to conduct prevention research activities designed to determine the efficacy of other biomedical or behavioral interventions that could prove of benefit in decreasing incidence of HIV infection in the population.

AIDS International Training and Research Program [AITRP] for the Far East and the Western Pacific.—Funds would be used to fill critical emergency needs related to containing the anticipated future explosion of HIV infection in the Far East and Western Pacific and to enhance existing program components to give a greater emphasis to the full range of training required.

The FIC provides analyses to the NIH, the PHS, the Department, the White House Office of Science and Technology Policy, and the Department of State on issues and legislation in the support of international science policy development and cooperation (for example, the General Agreement on Tariffs and Trade). The FIC is also responsible for the development and coordination of NIH international activities including bilateral and multilateral agreements (for example, the Department of State's initiative to increase U.S.-Japan cooperation in AIDS prevention) and for the provision of immigration and visa services for the foreign scientists in the NIH intramural research program. The reduction of five FTE's will adversely affect the FIC's ability in the future to respond to the increasing demands for analyses and support in these areas.

PREPARED STATEMENT

Dr. SCHAMBRA. If I may, Mr. Chairman, I have a prepared statement. May I submit it for the record?

Senator HARKIN. Yes; it will be made part of the record.
[The statement follows:]

STATEMENT OF DR. PHILLIP SCHAMBRA

Mr. Chairman, it is a pleasure to appear before this Committee to discuss the global role of the Fogarty International Center [FIC]. I am especially grateful for the opportunity to remind the Committee Members of our distinctive mission: to improve the health of the people of the United States—and the world—through international cooperation in biomedical research.

More than a generation ago, Congressman John E. Fogarty championed this mission with the words: "let our second American Revolution be a World War against disease." In the years during and following his courageous leadership in the House, a war was waged. Today, smallpox—once the deadliest of scourges—has been consigned to the ash heap of history. A battle is won but the World War goes on, for, as John Fogarty also said, "disease knows no national boundaries."

In this post-Cold War era, even as dramatic political changes have swept the globe, new adversaries have arisen. New diseases have emerged, and some once-vanquished diseases have returned, quietly developing resistance to our most potent drugs. The AIDS pandemic, and recent outbreaks of tuberculosis and cholera are cause for grave concern. Worldwide, population growth and demographic changes have exacerbated these and other health problems.

International collaboration improves the health of Americans by tackling such problems before they spread to our shores, by cross-fertilizing the ideas of researchers from around the world, and by pooling resources on large and complex efforts like genome research. Two recent examples stand out: (1) a gene for colon cancer was discovered through collaboration between a Finnish scientist (who once trained under a Fogarty Fellowship) and his colleagues in the United States; and (2) an Israeli scientist in the FIC's Scholars-in-Residence Program has isolated a gene associated with one form of leukemia.

The benefits of international collaboration were also recognized 25 years ago with the establishment of the FIC to serve a vital national need—as a nexus for the international activities of the National Institutes of Health [NIH]. Over the past year the Center celebrated its silver anniversary and, I am pleased to say, completed a major task: the development of a long-range plan that will guide us into the next millennium.

As Dr. Varmus has often noted, it is not a planning document that has value so much as it is the planning process itself. For the Fogarty Center that process has been both constructive and instructive as we faced the challenges and changing needs of the research community and the global laboratory.

From that process has emerged a clear set of goals. Our first priority must be the mobilization of international research against global health threats. To meet those challenges, we must work to advance science through international cooperation and to develop human resources for the future. The planning process also has allowed us to make strategic decisions in times of budget constraint. Let me now describe some of our programs.

AIDS tops the list of global health threats of concern to the Fogarty Center which supports the world's largest global research and training program in HIV/AIDS. This program develops human resources in regions of the world with high infection rates, laying hopeful groundwork for future vaccine trials. In 1993, roughly 17 per-

cent of NIH AIDS publications were authored or coauthored by an FIC-supported scientist in this program.

Genetic variability of the AIDS virus, and geographic differences in the features of the AIDS epidemic, make such an international approach essential. For example, a clinical trial in Haiti, where infection rates are high, has shown that the antibiotic isoniazid can decrease the incidence of tuberculosis and delay the onset of AIDS. These results have implications for HIV-infected individuals everywhere, including here in the United States where 5 to 10 percent of infected individuals may develop active tuberculosis within one year of diagnosis.

In fiscal year 1995, the FIC is planning to expand its AIDS research activities, strengthening these efforts through additional mechanisms including the new AIDS International Research Collaboration Award. This award will support top-caliber AIDS-related research collaborations between American and foreign scientists, including research on opportunistic infections, emerging and re-emerging pathogens, and diseases linked to factors known or suspected to be related to the spread of HIV.

Pathogenic microbes have always been major participants in human history—HIV is not the first nor will it be the last global epidemic. Historical epidemics such as Europe's black death, or tuberculosis and polio in modern times, have always been associated with changes in human behavior and migration. As the global population increases and urban population densities grow, and as human communities encroach on unfamiliar ecosystems, new and more virulent diseases are certain to emerge.

Thus, the FIC is developing a new program on Human Reproduction and Population Growth to enhance the population research activities of the United States. This program will promote international partnerships between U.S. and foreign scientists and institutions, building on existing efforts and adding an international dimension to ongoing domestic research. It will emphasize research collaboration with, and the training of, foreign scientists from developing nations to study and find solutions appropriate for their own regional concerns.

Global demographic changes also lead to a decline in the diversity of plants and animals, and a potential loss of beneficial medicines derived from these species. The FIC now supports and coordinates an International Biodiversity Program, joining U.S. and foreign scientists, indigenous peoples, and the private sector, to address biodiversity conservation and the discovery and development of new drugs to treat illnesses such as cancer, infectious disease, and mental disorders. Support is shared between the NIH, the Agency for International Development, and the National Science Foundation, pooling resources and programmatic expertise across the Federal Government to address cross-cutting scientific challenges.

Advancing science through international cooperation, and developing human resources are important goals for the Fogarty Center. The Center's prestigious Scholars-in-Residence Program and fellowships for the exchange of American and foreign scientists are significant components of this effort. In fiscal year 1995, FIC fellowships will emphasize new opportunities for young Americans to conduct research overseas, and the needs of scientists from less developed countries. In addition, with support from the NIH Office for Research on Minority Health, we have established an innovative new program to support minority students and faculty members in international biomedical research.

The FIC has responded quickly to global political changes. We now support an award program open to research collaboration with Latin America, sub-Saharan Africa, Central and Eastern Europe, and the new republics of the former Soviet Union. Scientists from the United States and the Czech Republic, for example, are studying mechanisms of viral assembly—important for designing the next generation of antiviral drugs. The FIC is now exploring mechanisms for a new Middle-East Research and Training Initiative to respond to positive political changes in that region.

In closing, let me note that as the world grows ever smaller our need to understand health and combat disease looms all the larger. The NIH remains a leader in this effort, but we have many allies—in Europe, in Latin America, in Asia and Africa. Today, the world is coming together in ways and at a pace never before seen; in this process, research to improve human health will be one of the great levers of change—advancing science, our national interests, and the cause of peace.

Thank you Mr. Chairman, the FIC budget request for fiscal year 1995 is \$13,745,000. I will be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. PHILIP E. SCHAMBRA

Date and place of birth: November 8, 1934, Saginaw, Michigan.

Education: 1956, B.A., Rice University; 1961, Ph.D., Yale University; 1961-63, Postdoctoral, Institut für Strahlenbiologie, Karlsruhe, Germany; and 1964-66, Postdoctoral, University of California, Berkeley.

Professional history: 1956-58, Research Assistant, Biophysics Department, Yale University; 1958-61, Predoctoral Fellow, National Cancer Institute, Biophysics Department, Yale University; 1961-63, Research Associate, Institut für Strahlenbiologie, Karlsruhe, Germany; 1964-65, Instructor, Department of Medical Physics, University of California, Berkeley; 1964-67, Research Biophysicist, University of California, Berkeley. NASA Research Fellowship; 1966, Laboratory Director, National Science Foundation Summer Institute in Radiobiology, University of California, Berkeley; 1967-68, Grants Associate, National Institutes of Health; 1968-71, Budget Examiner, Office of Management and Budget, Executive Office of the President; 1971-74, Staff Member, Council on Environmental Quality, Executive Office of the President; 1974-80, Associate Director for Interagency Programs, National Institute of Environmental Health Sciences, NIH; 1980-84, Chief, International Coordination and Liaison Branch, Fogarty International Center, NIH; 1984-88, Science Attache and PHS International Health Representative, U.S. Embassy, New Delhi, India; 1988-Present, Director, Fogarty International Center, National Institutes of Health.

Honors and awards: 1984, NIH Merit Award; 1989, PHS Superior Service Award; 1982-93, Outstanding Performance Ratings.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I appreciate it. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTION SUBMITTED BY THE SUBCOMMITTEE

Question. I understand that you have been assigned by NIH lead responsibility to develop and coordinate the response to the Senate's request last year that an international conference be held on biological diversity.

Please describe the status of the development and planning for the conference and its proposed agenda.

Answer. The FIC has been actively involved, along with other NIH components, in planning for an international conference on biological diversity in response to the Senate's request to the NIH on this matter. The FIC has been given this responsibility because of the lead role it has played in coordinating biodiversity activities throughout NIH.

To date a preliminary program has been developed and a scientific program committee is being appointed. The committee will meet on or about April 20 to review and refine the agenda. This program includes discussion of a number of key points including medicines derived from natural sources, NIH efforts to discover new drugs from biodiverse environments, sustainable development and biodiversity conservation, and intellectual property rights related to drug discovery from natural sources. Participants in the planning committee include representatives of interested organizations of physicians and other health professionals who are concerned with environmental issues. Invitations to speakers are expected to be extended by the end of May with plans to convene the conference in September or October this year in the Washington, D.C. area. All efforts are being made to incorporate the key points in the Senate's request as an integral part of this agenda.

NATIONAL CENTER FOR RESEARCH RESOURCES

STATEMENT OF JUDITH VAITUKAITIS, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Vaitukaitis, Director, National Center for Research Resources.

Dr. VAITUKAITIS. Thank you, Senator Harkin.

The National Center for Research Resources is quite different from the other Institutes and Centers represented around this table. Our major function is to provide the shared research resources and infrastructure to investigators who receive their primary research funding from the other Institutes and Centers in terms of investigator-initiated research.

During the past year we have had input from hundreds of investigators throughout the country in developing an action plan, and within the framework of that plan three major areas have been identified that would track very nicely into a 50-percent increase in our budget.

The first area is within molecular medicine and related technologies. One of the major needs of investigators has been to address the problem of handling animal models that have either induced genes or deleted genes that track to diseases or cell functions. We provide support for national resources for transgenics and knockouts. We need to markedly expand this area because of its rapidly evolving role in biomedical research.

Another area which has been identified by our colleagues in the extramural community has been the need for human applications laboratories. These laboratories would be the places where gene vectors are provided for human gene therapy and then distributed to other investigators regionally or nationally. We are in the process of developing a request for applications to establish several of these laboratories, in concert with our colleagues from the Heart Institute, the National Cancer Institute, the NIDDK, and the Genome Center.

These vectors will be provided not only for monogenetic diseases, but also for forms of cancer and for autoimmune diseases. Since gene therapy is in its infancy, this is the logical place to start to provide research resources on a shared basis. These human applications laboratories would be distributed in such a way that investigators from many universities would have access to those vectors through guidelines that are being developed with our colleagues.

Another area that has been identified as a high priority area is the further evolution of our high performance computing and communications activities. As technologies have become more complex, access for researchers to these complex technologies becomes more important.

For instance, there are only eight intermediate voltage electron microscopes available in this whole country. We are currently developing a technology called telemicroscopy which will allow an investigator sitting in this room to work at a work station, control the electron microscope in southern California, and have a technician put the sample up on the stage. The investigator at the terminal right here would control that electron microscope and decide what part of the tissue sample to look at. The information is provided in real time, and, using forms of high performance computing, the investigator can actually model the information that is gathered through that technology.

Telemicroscopy is ongoing now and we intend to develop it for other high-end technologies to make it easier for investigators to share access to complex technologies.

In the area of virtual reality, which is related to high performance computing, we are in the process of supporting and evolving ways of integrating sensory, motor, and brain functions, a technology we were unable to address before the development of this type of computing.

We also, through high performance computing, can already perform and need to extend our capability for stochastic modeling for various infectious diseases.

Infrastructure in the very broad sense has been identified as a major issue by the investigators throughout this country. Areas that need to be addressed include human resource development through science education for grades K to 12, and increasing public science literacy to enhance the pipeline for future scientists. We also need to broaden the knowledge of the public so they can make informed decisions about their lifestyles.

Continuing in the human resource development area, we need to further develop and evolve training for minority investigators in terms of career development, as well as for clinical research, to make them more competitive, to make sure research results are translated from the bench to the bedside. That is important and takes place mainly through our national network of clinical research centers.

Many of the clinical trials that you have heard discussed here today have been carried out through our network of clinical research centers, and it is an important part of the infrastructure to facilitate research.

We also now have authority for the bricks and mortar part of infrastructure, providing support for construction at biomedical research facilities.

PREPARED STATEMENT

We also provide instrumentation on a shared basis, the instrumentation that is too costly to be purchased by single investigators. We provide support for equipment that costs from \$100,000 up to \$400,000 to be shared by a number of investigators. This has been identified as a recurrent and pressing need. There are a number of other areas that have been identified in this whole planning process, but I wanted to highlight a few of the main points.

Thank you.

[The statement follows:]

STATEMENT OF DR. JUDITH VAITUKAITIS

Mr. Chairman and members of the committee, I am pleased to preview some of the National Center for Research Resources' plans to address the changing research resource needs of the biomedical research community. NCRR funds vital technologies and shared resources to undergird both basic and clinical research. As the pace of science accelerates, we must anticipate the needs of the nation's biomedical investigators for research infrastructure.

During the past year, NCRR solicited and received hundreds of recommendations from members of the scientific community. These recommendations are articulated in NCRR's recently completed strategic plan and have inspired some exciting initiatives. Today, I'll describe our plans for strengthening four high-priority areas—clinical research, animal models, high-performance computing, and infrastructure.

First, we will make our national network of clinical research centers increasingly responsive to promising new areas of science and to the country's health care needs. Over the past few decades, biomedical investigators learned to successfully transplant bone marrow, kidneys, livers, and hearts using the specialized staff and facilities of this network of general clinical research centers. Now scientists at these centers and other institutions are investigating a sophisticated, ultra-microscopic form of transplantation—gene therapy—that inserts human genes to develop new treatment for patients with cystic fibrosis, cancer, and immunologic disorders. Gene therapy is in its infancy. In the not-too-distant future, it may be used to treat sickle cell anemia, hereditary myopathies, hypertension, and eventually many other major diseases and disabilities of humankind. But to help gene therapy grow from infancy to its full potential, scientists across the nation need access to the vectors for gene therapy. So NCRR, along with several other institutes at NIH, is negotiating to provide regional gene therapy laboratories that will offer state-of-the-art resources that researchers can use on a shared and cost-saving basis.

The needs of groups with special health concerns—minorities, women, children—are addressed in GCRC portfolios, as well as the health problems of an aging population. Investigators at one of our clinical research centers have just reported that slow-release sodium fluoride, administered with calcium citrate, is a safe and effective short-term treatment for postmenopausal osteoporosis. If long-term use proves effective and safe, we may have found a new means to prevent fractures that cause disability, loss of function, and increased risk of death, particularly in older women.

Before research reaches the clinical stage, it almost always is conducted in an animal or other research model, which brings me to the second high-priority area. To support researchers conducting basic and pre-clinical research, NCRR will expand the range of animal and non-animal research models of human disease, especially models involving simpler life forms. Diseases for which animal models recently have been discovered or developed include Parkinson's disease, Lyme disease, and a variety of genetic disorders. NCRR-supported investigators recently reported that a dog model has the identical gene mutation as children with the most common form of inherited severe combined immunodeficiency disease. The animal model will be invaluable for developing new gene therapy techniques.

The pig-tailed macaque continues to evolve as an effective model for HIV-1 and HIV-2 studies. Pig-tailed macaques infected with HIV-2 decrease their CD-4 counts and develop symptoms just as people do. That animal model will be invaluable for developing vaccines and therapies for human AIDS.

Whether investigating AIDS or Alzheimer's, investigators need a wide range of research tools from which to choose. Research is most effectively advanced by a combination of models rather than by concentration on only a few. Thus, in 1995 NCRR will expand its resources for transgenic and targeted mutant animals. With such precise models, it becomes possible to study specific genes responsible for normal cell function as well as for human disease. NCRR is now encouraging the development of "high connectivity" models about which a large body of knowledge is already available and applicable to other systems. Hydras, lobster hearts, and clams, for example, provide insight for diagnosing and treating human cancers and birth defects, cardiomyopathies associated with Marfan's syndrome, and the effects of herbicides. And we support the development of marine models, including fish, abalone and sea urchins, that are useful models for the study of normal development from a few cells to the mature form.

The third area of emphasis in 1995 is to bring the benefits of high performance computing and communications to investigators. In collaboration with the National Science Foundation and other agencies, NCRR supports several high-performance computing resource centers that give investigators cost-effective access to some of the most powerful computers in the U.S. High-performance computing has enabled development of powerful molecular graphics to examine the structure of proteins

and uncover their function. Image analysis and the study of biological structures also depend heavily on high-performance computing, as do advanced graphics and biological modeling. An NCRR-supported NMR microscopy resource will allow scientists not only to see anatomic changes in genetically altered mouse embryos through 3-D reconstruction of a "virtual embryo," but also to monitor that viable embryo over time to better understand the impact of genetic modifications.

To make research technologies even more accessible in the future, NCRR-funded investigators are developing a technique known as telemicroscopy, which links expensive and scarce instrumentation such as a high-voltage electron microscope via a high-speed communication network—to create a distributed laboratory across this country. Only eight such microscopes are available to U.S. biologists. The first long-distance experiment linked a high-voltage electron microscope in San Diego with a computer workstation in Chicago. In the future, we foresee that scientific information highways will link scientists to other sophisticated technologies.

Our fourth initiative will be to create better ways to meet the research and health needs of underserved populations. NCRR will continue to expand clinical research for underrepresented groups at academic institutions. This initiative will help increase minority participation as investigators, boost minority representation in research protocols, and expand research on health problems of minority populations. NCRR also will emphasize training of minority physicians and dentists to become independent clinical investigators. In addition to these clinical, research model, technology, and minority health initiatives, NCRR has many other exciting plans. To mention only a few, we will expand support of biomedical engineering technologies to improve the monitoring of research studies, ultimately to improve patient care. In addition, NCRR will stimulate technological research and development of novel, cost-efficient approaches to disease prevention and medical treatment. These technologies include sensors, physiologic monitoring systems, and "smart" drug delivery systems. We also plan increased funding for shared instrumentation grants which allow 8 to 10 NIH-supported investigators to purchase a state-of-the-art instrument such as a mass spectrometer or DNA sequencer. These vital instruments are too costly for individual scientists to purchase with funds from regular research grants. We also plan to award grants for construction and modernization of academic research facilities as part of a program to enhance the Nation's scientific research infrastructure.

NCRR's programs are unique and diverse. I will conclude by saying that many people take roads, bridges, and other infrastructure for granted until an Act of God—earthquake, mud slide, hurricane—destroys it. Funds spent on infrastructure may not seem as glamorous or as high-priority as that spent on specific diseases. But infrastructure funds permanently benefit the institutions to which they are awarded, strengthen biomedical research, and—most important—improve the health of the American people, for whom all this effort ultimately is intended.

Thank you, Mr. Chairman. The non-AIDS request for the National Center for Research Resources is \$286,394,000. I would be pleased to answer any questions you may have.

BIOGRAPHICAL SKETCH OF DR. JUDITH L. VAITUKAITIS

Birth place: Hartford, Connecticut.

Education: B.S., Tufts University, 1962; M.D., Boston University School of Medicine, 1966; Internship and Residency, Second (Cornell) Medical Service, Bellevue Hospital, NY, NY, 1966–68; Medical Resident, University Hospital, Boston, MA, 1968–69; Academic Training Fellow, Boston University School of Medicine, 1968–71; Endocrine Section, National Cancer Institute, NIH, Bethesda, MD, 1970; Special PHS Postdoctoral Research Fellow, Reproduction Research Branch, NICHD, NIH, Bethesda, MD, 1971; Senior Staff Fellow, Reproduction Research Branch, NICHD, NIH, Bethesda, MD, 1971–73.

Professional history: March 1993 to present, Director, National Center for Research Resources (NCRR), NIH; 9/92 to 3/93, Acting Director, NCRR, NIH; 6/91 to 3/93, Deputy Director for Extramural Research Resources (ERR), NCRR, NIH; 2/15 to 6/3/90, Acting Deputy Director, ERR, NCRR; January 15 to February 15, 1990, Acting Deputy Director, Division of Research Resources; 6/91 to 11/92, Acting Director, General Clinical Research Centers (GCRC) Program, NCRR; 1986–91, Associate Director for Clinical Research and Director, GCRC Program, NCRR; 1977–86, Professor of Medicine, Boston University School of Medicine (BUSM); 1980–86, Professor of Physiology, BUSM; 1974–86, Head, Section of Endocrinology and Metabolism, Boston City Hospital, Boston, MA.; 1975–86, Program Director, General Clinical Research Center, BUSM; 1977–80, Associate Professor of Obstetrics and Gynecology,

BUSM; 1975-80, Associate Professor of Physiology, BUSM; 1974-77, Associate Professor of Medicine, BUSM; 1974-75, Guest Worker, Reproduction Research Branch (RRB), NICHD, NIH, Bethesda, MD; 1973-74, Senior Investigator, RRB, NICHD, NIH, Bethesda, MD.

Societies and Associations: Association of American Physicians; American Society for Clinical Investigation; American Federation for Clinical Research; The Endocrine Society.

Honors and awards: 1987-89, Associate Editor, Yearbook of Endocrinology; 1984-86, Editorial Board, Endocrine Research; 1979-84, Editorial Board, Endocrine Research Communications; 1978-87, Editorial Board, Proceedings of the Society for Experimental Biology and Medicine; 1977-85, Editorial Board, Archives of Andrology; 1973-80, Editorial Board, Journal of Clinical Endocrinology and Metabolism; 1983, Distinguished Alumna Award, Boston University School of Medicine; 1980, Mallinckrodt Award for Investigative Research, Clinical Radioassay Society; 1983-86, General Clinical Research Centers Committee, Division of Research Resources; 1979-80, Population Research Committee Study Section, NICHD; 1977-80, Scientific Advisory Committee, Program for Applied Research on Fertility Regulation, Aid to International Development; 1975-78, Breast Cancer Task Force, Epidemiology Subcommittee, National Cancer Institute; Alpha Omega Alpha; Begg (honor) Society.

Publications: Author of over 160 scientific papers with four selected as Citation Classics; editor of one book.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Vaitukaitis.

In the legislation that Senator Hatfield and I have proposed we have set aside 2 percent for construction purposes.

Dr. VAITUKAITIS. We will be pleased with that help.

Senator HARKIN. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

EXTRAMURAL CONSTRUCTION

Question. Prompted by the Senate, Congress appropriated \$7 million for extramural construction for fiscal year 1994. Please detail the current status of this effort.

Answer. A request for construction grant applications was issued in January 1994. The application receipt date is April 8, and following peer review, the \$7 million in grants will be awarded in September. Since this is a matching grant program, these awards will fund at least \$14 million in research facility construction. The NCRH expects over 100 competing applications for the available funds.

Question. In your estimation, what is the real need out there for extramural construction?

Answer. The NIH has been assessing the need for extramural research facility construction through a survey done every two years on the status of biomedical research facilities. The 1992 survey, published in 1993, suggested that about one-third of the research space in biomedical research institutions was inadequate to meet the requirements of current research programs. The expected 100 competing applications for the available funds represents another testimony to the need for this authority and funding.

INSTITUTIONAL DEVELOPMENT AWARD PROGRAM

Question. In its fiscal year 1994 Committee Report, the Senate directed NCRH to expand its funding for the Institutional Development Award [IDeA] program. As you know, this program, patterned after a similar program developed by the National Science Foundation, is very popular with Senators representing smaller universities. Please describe your efforts to respond to this language.

Answer. The IDeA program was implemented in fiscal year 1993 with six awards totaling \$750,000. The program provides infrastructure support to institutions in the EPSCoR states as well as to states that have historically low success rates in

obtaining NIH research funds. The primary goal is to increase sustainable long-term growth in institutions in these states in order to broaden the geographical distribution of NIH funding for biomedical research. Upon a congressional request all accredited Schools of Chiropractic Medicine were included.

The fiscal year 1994 appropriation for NCRR includes \$785,000 for ten awards, an increase of \$35,000 or 4.7 percent, the same level of increase as provided for other NCRR programs.

GENE THERAPY

Question. Your Center's resource programs underpin many of the most critical and most advanced research activities supported by NIH. Please explain how the NCRR resources support NIH research in molecular medicine and in particular in gene therapy.

Answer. Advances in molecular medicine are leading to opportunities to test treatments and possible cures for diseases through gene therapy. Anticipating these medical breakthroughs, the General Clinical Research Centers (GCRC) Program is supporting laboratories for vector production and human applications for gene therapy at some GCRC sites. Resources, including hospital beds, research nurses, and specialized laboratory facilities for administering gene therapy to patients and following their courses are available widely throughout the GCRC's. These resources have enabled experimental administration of gene therapy at GCRC's: for cystic fibrosis—at the University of Iowa, at the University of Pennsylvania, and at the University of North Carolina; for familial hypercholesterolemia—at the Universities of Michigan and Pennsylvania; and for severe combined immunodeficiency at the University of California at San Francisco. Clinical researchers at other GCRC sites are preparing for studies involving other diseases such as Gaucher's disease and cancer.

NCRR ACTION PLAN

Question. I understand that the National Center for Research Resources recently completed work on an NCRR action plan. This would be the first plan of its kind for the Center.

Please describe the plan and its relation to the Center's principle objectives in research opportunities for 1995 and beyond.

Answer. NCRR's mission is to serve as a "catalyst for discovery" for NIH-supported investigations throughout the Nation. We do this by creating, developing, and providing a comprehensive range of human, animal, technological, and other resources to enable biomedical research advances. NCRR promotes collaborations within and across scientific disciplines and provides quick, flexible approaches to new and emerging research needs.

The greatest challenges facing the NCRR in fulfilling its mission are to keep abreast of rapidly evolving trends in basic and clinical research and to respond by offering NIH-supported scientists a comprehensive range of tools and materials critical to their research efforts. To tackle these challenges, NCRR has undertaken an interactive, open planning process in partnership with the broad scientific community. The NCRR Plan reflects the considerable input from that community and provides guidance to NCRR and the NIH in making the difficult choices between many competing priorities in times of tight fiscal constraints.

When making difficult choices, NCRR must give priority to those projects for which it is the best or only source of support. The following characterize NCRR resources and technologies:

- At the cutting-edge in technologies and research, including high-risk research that may have high payoff.
- Often one-of-a-kind, scarce, or expensive.
- Accessible and responsive to the research needs of the biomedical research community.
- Cost-saving, efficient, and shared.
- Multidisciplinary and collaborative, often serving to integrate diverse research efforts.
- Stable and flexible, allowing scientists to react rapidly and effectively to emerging research needs and unexpected opportunities.

As part of the Plan, NCRR has developed objectives and opportunities in broad research areas for fiscal year 1995. The following are some examples:

Objective.—Ensure that the clinical research community has sufficient research resources to respond rapidly and effectively respond to current and emerging critical health issues.

Opportunity.—Gene Therapy Human Applications Laboratory—Integrate and expand research collaborations in molecular medicine to meet the needs of other NIH

Institutes. NCRR is collaborating with the National Heart, Lung and Blood Institute, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Cancer Institute, and the National Center for Human Genome Research to develop regional human applications laboratories for gene vectors for human therapy.

Objectives.—Foster multidisciplinary research projects and serve to integrate diverse research efforts. Promote development of and accessibility to novel and essential tools and support cutting-edge technologies.

Opportunities.—High Performance computing and Communications—Develop (1) image analysis, including real time imaging; (2) software for group cooperative work and use of networks, e.g. telemicroscopy; (3) virtual reality—a computing system that integrates the human into a complex visual environment—for understanding protein structure and function; studies of the linkage of visual-motor control, perception, and cognitive psychology; and teleconsulting and surgery. Continue to develop algorithms for protein folding simulations and calculations of free energy of solvation; accelerate protein structure determination using NMR data; investigate binding of drug molecules to receptors of known crystalline structure; integrate graphics and molecular dynamics for problems of protein design. Stimulate technological development of novel, cost-effective bioengineering approaches to disease prevention and control to impact critical health areas and reduce health care costs. Develop innovative devices, sensors, instruments and methodologies, and demonstrate their effectiveness in humans. Encourage approaches that are noninvasive or minimally invasive, stable, long-lived, reliable, low-power consumers, able to provide data in real time, and tolerant of harsh environments.

Objective.—Promote the development, availability, and accessibility of animal and nonanimal models for human health and disease.

Opportunities.—Establish a National Resource for Transgenic Animals—Extend national resources to: (1) develop new animal models, stem cell lines, and related technological tools; (2) preserve germ plasm of valuable experimental models such as unique knockout strains and spontaneous models in jeopardy of extinction; and (3) catalog and distribute them.

Marine/Freshwater Research Resources—Improve and develop aquatic life research resources by supporting facilities with strong links to funded biomedical scientists. Establish facilities to develop, maintain, and supply genetically homogeneous strains—including transgenic organisms—at reasonable cost, and provide access and training for investigators.

Objective.—Improve and maintain the Nation's biomedical research infrastructure.

Opportunity.—Extramural Research Facilities Construction Program—Mandated by the NIH Revitalization Act of 1993 and initiated in 1994, this program supports construction of biomedical and behavioral research facilities. Specific targets include "Institutions of Emerging Excellence," Regional Primate Research Centers, and institutions that promote genomic, interdisciplinary research related to pediatrics.

Objective.—Ensure the growth and strength of the Nation's scientific talent base.

Opportunities.—Expand Number of Minority Clinical Research Investigators and Participation of Minorities in Clinical Trials—Expand Minority Clinical Associate Physician Award Program to develop physicians and dentists as independent clinical investigators. Expand clinical research at minority institutions by providing satellites to established clinical research centers. This thrust is two-fold: to increase minorities both as investigators and as research subjects.

QUESTION SUBMITTED BY SENATOR HATFIELD

REGIONAL PRIMATE CENTERS

Question. Dr. Vaitukaitis, as the Director of the Center for Research Resources at the NIH, you have the responsibility for overseeing the Regional Primate Centers program. I am told by the staff at the Oregon Regional Primate Center that there is a tremendous need for construction and renovation funding at the centers. Would you agree? Have you done an analysis of the facility needs at these centers? What role do these centers play in the national biomedical research program?

Answer. A need exists at the seven regional primate centers for substantial alterations and renovations and expansion of their current facilities which were initially built over 30 years ago. Since those primate centers serve as national resources, there is little incentive of the host universities to infuse large sums of funds to upgrade those facilities. The primate centers play an irreplaceable role in AIDS-related research with nonhuman primate models. No other significant facilities exist in this country.

AIDS-related research requires specially adapted facilities to protect both the scientists and animal technicians who interact with virus-infected live animals and their tissues. More research space has been targeted for this important research over the past 10 years and that has compromised the research space for other research areas—e.g. Parkinson's, Alzheimer's, Sudden infant death syndrome and many other areas. The seven regional primate centers host over 1,300 scientists who receive primary research funding from the other components of the NIH, other Federal agencies as well as from the private sector.

QUESTIONS SUBMITTED BY SENATOR COCHRAN

INSTITUTIONAL DEVELOPMENT AWARDS

Question. Last year the National Center for Research Resources made six awards totaling approximately \$750,000 under the Institutional Development Award (IDeA) program. These awards were made to South Carolina, Idaho, Maine, Montana, Oklahoma, and Wyoming.

Please describe these projects.

Answer. The following is a description of the IDeA projects funded in fiscal year 1993:

1. State: Idaho.

Institutions: Idaho State University and University of Idaho.

Project objective: To create interactive relationships among the multidisciplinary biomedical researchers in Idaho.

Faculty development workshops, symposia and seminars which included the following six pilot research projects: Neuroendocrinology studies on the regulation of gonadotropin releasing hormones; studies on the effects of estradiol and progesterone on the function of opioid receptors in neuronal cells; the role of calcium regulation in skeletal and cardiac muscle function and the role of calsequestrin in illness mediated by cellular calcium overload; studies to assess whether calcium antagonists bind irreversibly to proteins; studies on the molecular basis of regulon repression in the facultative parasite *Yersinia enterocolitica*; and *saccharomyces cerevisiae* as a model to test the prediction that allelic variants will have negligible effects on metabolic flux.

2. State: Maine.

Institution: Jackson Laboratory, Maine Medical Center, Foundation for Blood Research, Saint Josephs Hospital, and Eastern Maine Medical Center.

Project objective: To transfer basic research findings to therapeutic strategies by creating alliances between Jackson Laboratory and other clinical research institutions in Maine. Four research projects focus on osteoporosis, atherosclerosis, cystic fibrosis and cancer.

3. State: Montana.

Institution: Montana State University and University of Montana.

Project objective: To enhance biomedical research in Montana by combining long-term planning with implementation of projects for faculty development. Specifically, support was provided for two pilot projects by junior faculty for: Using a valid ischemia rodent model to study the biochemical characteristics of neurons that are sensitive to ischemia and to grow fungi with significant antifungal activity or cytotoxicity and characterize the bioactive components.

Support for infrastructure including: Development of a central facility to over express and purify cloned proteins and support for development of new techniques for mass spectrometry of biologically active compounds.

4. State: Oklahoma.

Institution: University of Oklahoma Health Sciences Center and Oklahoma State University.

Project objective: A comprehensive plan to assist junior faculty from major research institutions in Oklahoma to develop into competent biomedical researchers. Six multidisciplinary projects in molecular biology and medicine to focus on immunology, cell membrane biology, neuroscience, signal transduction, receptors, biotechnology and clinical epidemiology.

5. State: South Carolina.

Institution: Medical University of South Carolina, University of South Carolina, and Clemson University.

Project objective: Development of a facility for generating transgenic mice to enhance basic and clinical research in molecular medicine. Specifically funds supported: Pilot projects to develop knockout mice for glutathione-S-transferase and

thymidine synthetase to determine their role in carcinogenesis and faculty development to stimulate research activities at Clemson University.

6. State: Wyoming.

Institution: University of Wyoming.

Project objective: To strengthen research activities in the area of structural biology especially in the study of macromolecular structure and its relationship to biological function. Support was provided for three pilot projects by junior faculty members for: The structure and function of bovine uterine protein, collagen structure and its relationship to heart function post-myocardial infarction, and enzyme-mediated catalysis and regulation of two enzymes in gluconeogenesis.

Question. What happens next to these six award recipients? How will they be integrated into regular NIH research programs?

Answer. The first six one-year IDeA awards were made in September 1993. These projects are currently midway through the grant period, and therefore it is too early to evaluate the program impact on integration of these projects into the regular NIH research programs. Those recipients may also compete in the fiscal year 1994 program for research different from that funded initially in September 1993.

Question. In its fiscal year 1994 Labor-Health and Human Services Appropriations, the Committee directed the National Center for Research Resources to increase its funding for the IDeA program over the 1993 level, to include all states designated by the National Science Foundation as eligible to participate in the EPSCoR program, and to use state-based EPSCoR committees in review process.

How is NIH planning to meet these directives?

Answer. The funding for the program was increased in fiscal year 1994 to a level of \$785,000 from \$750,000 in fiscal year 1993 and a new request of applications was issued for the IDeA program. All states designated by the National Science Foundation as eligible to participate in their EPSCoR program were eligible to apply for the NIH program and state-based EPSCoR-like committees participated in the selection process as directed by the Committee. Additional states with total funding less than \$30 million from the NIH in fiscal year 1992 are also eligible.

Question. IDeA proposals were submitted by the states in February. What happens next?

Answer. Proposals were submitted by institutions within eligible states and will go through the NIH merit-based peer review process. Review of IDeA applications for scientific and technical merit will be performed by an ad hoc review committee convened by the Office of Review, NCRR. Applications will undergo a second level of review by the National Advisory Research Resources Council. It is anticipated that the most meritorious applications will be funded by September 1994.

Question. How will the applicants that are successful in this round be integrated into NIH's research program?

Answer. It is anticipated that under the support of the IDeA grants, the participants will be able to generate pilot data and to lay strong foundations for their research that will allow them to compete for regular NIH grants in the future.

Question. Does the fiscal year 1995 budget contemplate any additional rounds of IDeA grant competition? Please explain.

Answer. The fiscal year 1994 awards will be two-year awards. Most of the funds in the proposed fiscal year 1995 IDeA budget will be used to fund the second year of fiscal year 1994 grants. Another round of grant competition for the IDeA Program is not contemplated for fiscal year 1995, although one or two additional awards may be made from the pool of fiscal year 1994 applicants.

Question. How will NIH's IDeA program coordinate with the EPSCoR programs at the National Science Foundation and other federal agencies?

Answer. At this time coordination with EPSCoR programs at the National Science Foundation and other Federal agencies is mainly carried out at the state level. Each state assesses its own capacity in biomedical research and, using established EPSCoR committees supplemented with researchers in biomedical areas, solicits applications and selects the one application from each state which will be submitted to compete at the national level. Several states participate in the NIH IDeA program which are not included in the NSF EPSCoR program; those states coordinate to select the applicant institution for the NIH program. The research mission of the NIH differs significantly from that of other Federal agencies. NCRR staff provide technical assistance directly to representatives from the eligible states and Schools of Chiropractic.

NATIONAL INSTITUTE OF NURSING RESEARCH

STATEMENT OF DR. ADA SUE HINSHAW, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Hinshaw, Director of the National Institute of Nursing Research, is also, sad to say, leaving us.

Dr. HINSHAW. Yes; and I would like to start off by saying thank you to you, Senator, and to the committee. You have seen us through the founding of nursing research at the NIH in 1986 to our Institute status in 1993.

Senator HARKIN. That is right.

Dr. HINSHAW. You have been very important and very facilitative for us. Many thanks.

Senator HARKIN. You have done a great job.

Dr. HINSHAW. We also appreciated having you with us at the night-in-gala in November to celebrate the establishment of the National Institute of Nursing Research. That was delightful.

Senator HARKIN. That was nice.

FIFTY-PERCENT INCREASE

Dr. HINSHAW. In terms of your first question, which was what would a 50-percent increase in budget accomplish, that would be a godsend to the National Institute of Nursing Research. We are facing a 10- to 12-percent success rate, so we are funding 1 out of 9 or 10 approved applications.

The problem is what happens to scientific productivity and the morale of the nurse scientists we are working with. So the low-success rate is a concern from several directions.

The important thing is really the science itself, and we have launched several very important areas of study, for example, health promotion and prevention of disease in younger children. For the last 2 to 3 years we have had an initiative in the area of health promotion with adolescents and older children. We have discovered that, as exciting as those findings are and as much as we have learned about encouraging healthy lifestyles for adolescents, we are already too late. We have to back up and begin to work with much younger children to help them form healthy habits that will last all their lives.

We need to do the basic behavioral and cognitive development research, as well as develop motivational interventions for younger children.

A second area of research that we are very excited about is symptom management of different diseases and treatments. In this next year we will be focusing on symptom management with HIV-infected individuals—studying such symptoms as high levels of fatigue, which can be very destructive and very hard to handle, as

well as nausea and vomiting. These symptoms can compromise compliance with therapies.

To cite another area, we are currently funding a large number of studies with the National Institute on Aging on symptom management with Alzheimer's disease patients. These studies are aimed at helping families know how to handle eating problems, dressing problems, confusion, and wandering behavior. We are quickly arriving at the point where we need to move to clinical trials.

So a 50-percent increase would really be a godsend in terms of being able to elaborate these single studies and interventions, which are very promising, into clinical trials.

PREPARED STATEMENT

Finally, I would like to mention an area that can have a major impact on health care reform. We are funding studies that look at new practice models, where physicians and nurses work together to reduce costs while maintaining the quality of health care. I could tell you much more about that, but given the time, I do not want to cut out my other colleagues.

[The statement follows:]

STATEMENT OF DR. ADA SUE HINSHAW

Mr. Chairman, I am pleased to be here today, particularly because I can speak for the first time about the programs of the National Institute of Nursing Research. We appreciate the tremendous support you in Congress have given us—support that has made possible our becoming an Institute at the NIH.

At this stage in our short history, the Institute is building on its scientific foundation, which has already begun to produce findings for nursing practice and to suggest important next steps in furthering scientific knowledge for better health.

I would like to begin by discussing preliminary findings that show promise in the near future. A study of newborns' sucking patterns, for example, may provide a window into the developing brain of very low birthweight babies and help predict neurobehavioral damage. As this chart shows, when we compare sucking patterns of premature infants with those of full-term infants, we see a dramatic difference. The preterm infant's sucking patterns are short, frequent bursts of sucking, whereas the full-term infant's patterns show bursts of longer duration, indicating, among other things, efficiency in consuming more milk. After following infants for six months, there was evidence of the ability to predict their developmental progress based on their initial sucking patterns.

Moving from the very young to older people, a study to reduce the impact of falls of our senior citizens has produced a pad, worn at the hip joint, that may prevent fracture of the hip, which happens to 250,000 people each year. The cost is high, both in human terms—24 percent die within a year, and monetarily—\$7 billion annually. As you can see, the pads are quite thin, yet they are believed to be capable of dispersing the force of a fall and avoiding fracture. The pads are inserted into side pockets of a garment that holds them into place over the hip joints. Engineering these hip pads, however, was not a straightforward process. Originally the pads were much thicker and larger, but in the testing phase older people thought they were bulky and difficult to wear under their clothes. Women in particular thought the pads made them look too heavy. With these thinner, more efficient pads, the compliance trend has gone up, with the study group wearing them 75 to 80 percent of their waking hours. Still, there are some compliance inhibitors to be overcome to assure greater success, such as difficulties with cognition and dementia.

A prevalent treatment for cancer, chemotherapy, causes nausea and vomiting in as many as 3 of every 4 patients, even when anti-nausea drugs are used. These side effects are serious in that they can cause patients to stop therapy and severely hamper their fight of the disease. Cancer-fighting drugs do not address the patient's expectations of being sick, whereas systematic desensitization techniques are effective in reducing patient's preconceptions and adverse response to both chemotherapy and anti-nausea drugs. An NINR-funded study builds on a behavioral intervention that

is quite effective in reducing the incidence and severity of nausea and vomiting. The investigator has found a way to predict who is at high risk for these side effects. As cancer progresses and drugs become more potent to combat it, the in-tandem behavioral therapy is realigned to counteract the possibility of progressively severe reactions.

Turning from preliminary findings to four areas that the Institute would like to channel ongoing and future research, we want to expand knowledge about influences in childhood that affect later healthy or risk taking behaviors. We want to know more about how to relieve the symptoms of HIV infection and its treatment and improve patients' quality of life. We want to continue to develop interventions at the community level that are culturally sensitive and that focus on populations that are particularly vulnerable to diseases or risky behaviors. And we want to continue to address women's health issues, such as breast cancer.

Although pre-teen and teen years are when risky behaviors often surface, researchers are in the dark about how teens' health habits are shaped by their early childhood experiences and what can be done to manipulate these childhood precursors so that health promoting, and not risk taking behaviors develop. How can we help children govern certain biological predispositions, such as weight gain, or ability to control stress? How can we help them avoid the future consequences of smoking or drugs? What can health practitioners do to promote positive parental influences in the child's early years, or assess and correct psychological factors, such as poor self esteem, before they lead the child into trouble? The Institute wants to build on current health promotion studies with adolescents to find answers to these questions. Right now we are funding studies to reduce risk factors for cardiovascular disease through education or aerobic exercise; assess the effect of mother-child interactions to the child's behavior and sense of control; and compare children who were either low birthweight or full-term infants to assess their later health, success in school, and behavioral and cognitive competencies. But we need to know more about how the environment, together with biological and cognitive characteristics, affect the child's later selection of risk-taking and health promoting behaviors.

As to the future directions of our intramural program, which we believe to be a showcase for successful collaborative efforts with other institutes, I would like to focus on our HIV studies. We are collaborating in this case with the National Institute of Allergy and Infectious Diseases and are studying interventions to alleviate symptoms and improve the quality of life for AIDS patients. Currently there is a focus on nutritional changes, which make the appetite very temperamental, and muscle weakness during treatment regimens. This year research will be expanded to focus on such issues as fatigue and specific coping factors for maintaining quality of life, despite the downhill course of the illness. A new extramural initiative leading to large-scale clinical studies will include non-drug strategies to ease physical symptoms and investigation of why patients respond differently to symptoms and treatments.

A notable strength in the nursing research base is studies at the community level that target health care issues of special populations, such as minorities, or people particularly vulnerable to disease. The diverse beliefs and experiences of people of different ethnic and cultural backgrounds are integral to developing health care interventions. For example, we support research that develops and tests school-based interventions that lower cholesterol levels in high risk children; culturally-sensitive prenatal care for Hawaiian, Japanese and Filipino women; and special health care support for low-income African American women who are at risk for premature labor. The fiscal year 1995 priority of the National Nursing Research Agenda, the Institute's long-range plan, reinforces the theme of community-based health care research for the vulnerable, the underserved, the inner city and rural minorities. Our focus will be on primary, rehabilitative and convalescent therapies.

I want to just mention that women's health research, another strength of the Institute, will also continue to expand its base of studies, with emphasis in fiscal year 1995 on management of symptoms associated with medical treatment for breast cancer, as well as on symptoms typically experienced by women in mid-life, such as hot flashes, insomnia, and gastrointestinal problems.

Another future direction for the Institute and, indeed, the nation, is health care reform. Let me give you two examples of studies that tie in nicely with the twin health care goals of improved quality and reduced cost. One study compared cost savings and clinical outcomes of patients who were chronically critically ill and were in either the hospital's regular intensive care unit or a special intensive care unit managed by nurses. Preliminary findings indicate that in the special unit, the patients' mortality and morbidity rates were lower, their satisfaction was higher, and their costs were about 7 percent less. Another study was planned and conducted by nurse-midwives and physicians in order to redefine practice to maintain quality and

lower costs of prenatal, labor, delivery and postpartum care. Preliminary results indicate many similarities but also some differences in approach. The nurse midwives used more low-tech interventions, such as psychological support and monitoring the patient through observation and listening, rather than through equipment and drugs. Further, hospital stays were shorter, maternal morbidity was lower, patient satisfaction was higher, and total charges were almost 10 percent lower for the mother.

In closing, as I reflect on eight years of nursing research at NIH, I am proud to have been in at the creation and to have seen the growth in size and relevancy of nursing science in addressing the nation's most pressing health issues.

Thank you, Mr. Chairman. The fiscal year 1995 budget request for this Institute is \$48,326,000. I will be pleased to answer any questions you might have.

BIOGRAPHICAL SKETCH OF ADA SUE HINSHAW

Born: May 20, 1939, Arkansas City, Kansas.

Education: B.S., University of Kansas, Lawrence, Kansas, 1961; M.S.N., Yale University, New Haven, Connecticut, 1963; M.A., University of Arizona, Tucson, Arizona, 1973; Ph.D., University of Arizona, Tucson, Arizona, 1975.

Professional history: 1963-65, Instructor and Chairperson, Maternity Nursing Section, University of Kansas, Lawrence, Kansas; 1966-67, Assistant Professor, School of Nursing, University of California, San Francisco, California; 1968-71, Administrative Coordinator, First Year Undergraduate Program, School of Nursing, University of California, San Francisco, California; 1971-75, Masters' and doctoral studies, University of Arizona, Tucson, Arizona; 1975-87, Liaison Position: Director of Nursing Research, University Medical Center, Tucson, Arizona and Professor and Director of Research, College of Nursing, University of Arizona, Tucson, Arizona; 1987-Present, Director, National Institute of Nursing Research, National Institutes of Health.

Professional organizations: American Academy of Nursing, American Nurses' Association (ANA), ANA Council of Nurse Researchers, Arizona Nurses' Association, Sigma Xi, Western Society for Research in Nursing, Sigma Theta Tau, National Academies of Practice, Institute of Medicine.

Honors and awards: Kay Schilter Award, University of Kansas School of Nursing, 1961; Lucille Petry Leone Award, National League for Nursing, 1971; Wolanin Geriatric Nursing Research Award, University of Arizona College of Nursing, 1978; Sigma Theta Tau, Beta Mu Chapter, Award for Excellence in Nursing Education, 1980; Alumni of the Year Award, University of Kansas School of Nursing, 1981; Distinguished Alumni Award, Yale University School of Nursing, 1981; Nurse Scientist of the Year Award, American Nurses' Association, 1985; Elizabeth McWilliams Miller Award for Excellence in Research, Sigma Theta Tau International, 1987; Doctor of Science Degree, University of Maryland, 1988; Doctor of Science Degree, Medical College of Ohio, 1988; Doctor of Science Degree, Marquette University, 1990; Alumni Achievement Award, University of Arizona, 1990; Distinguished Service Citation, University of Kansas, 1992; Doctor of Science Degree, University of Nebraska, 1992; Doctor of Science Degree, Mount Sinai Medical Center, 1993; Health Leader of the Year Award, PHS, 1993.

HEALTH CARE REFORM

Senator HARKIN. I am glad you made those points. If you had not I would have asked you questions about them, because with the health care reform bill coming through, I do not know exactly how it is going to take shape, but I envision a much increased role for nurses, nurse practitioners, and nurse midwives, and I do not know that we have done much research into the structure of it.

Dr. HINSHAW. We are just beginning to.

Senator HARKIN. And what is the most effective structure and the most effective use.

Dr. HINSHAW. Exactly, and how we do that working with our physician colleagues.

Senator HARKIN. Thank you.

Where are you headed?

Dr. HINSHAW. The University of Michigan, back to academia.

Senator HARKIN. Very good. I am sure we will be in touch. Knowing your background, I am sure we will.

Dr. HINSHAW. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HEALTH CARE REFORM

Question. How can nursing research assist us in reforming our nation's health care system? Can you provide some specific examples of areas where nursing research has improved health care delivery that have either resulted in lower costs to the consumer or improved accessibility to health care?

Answer. Balancing high quality health care with cost containment is one of the most striking challenges of health care reform. Some current NINR-sponsored research studies have preliminary findings that include important cost implications. For example, one study is comparing the care of low-risk women before, during, and after childbirth by certified nurse-midwives and by physicians in terms of quality and cost savings. Patients of the nurse-midwives showed lower maternal morbidity and higher satisfaction with care, and total charges were almost 10 percent lower for the mothers (baby care charges were the same). Another study investigated the impact on health care quality and cost of clinical nurse specialists providing transitional home follow-up care when patients are discharged from the hospital early. Cost savings were 29 percent for women having cesarean births; 38 percent for new births, 38 mothers with diabetes, and 6 percent for women with hysterectomies. In all these populations, the quality of care was maintained or enhanced.

There are many provisions in the health care reform proposals that could be informed by nursing research. Among these are examinations of strategies to provide effective health care in the community, especially to vulnerable and underserved populations residing in inner cities and rural areas. NINR will target research on community-based health care models as a priority in fiscal year 1995. This initiative will focus on increasing our understanding of the influence of cultural and behavioral factors on the effectiveness and outcomes of health care, and our capability of providing culturally sensitive and acceptable clinical treatments and interventions. The emphasis will be on vulnerable and underserved populations.

In addition, nursing research may inform other aspects of change that will be vitally needed to implement whatever health care reform proposal is enacted. For example, new ways to organize acute hospital care will continue to be needed, particularly testing of clinical management strategies designed to maintain quality while achieving cost savings. NINR is currently funding such a study which, if preliminary findings are substantiated, has the potential of reducing the hospital costs for patients needing intensive care over a long time period. These chronically critically ill patients tend to be very costly to individual hospitals and thus to the Nation's health care system.

LOW BIRTH WEIGHT AND INFANT MORTALITY

Question. The incidence of low birth weight and infant mortality continue to be of major concern for minorities. What is the NINR doing to improve the health of pregnant women and their infants?

Answer. NINR has a significant investment in research dealing with both the prevention and care of low birth weight infants, with a particular focus on minority populations. For example, the effect of a community-based nursing intervention to promote optimum fetal development and prevent premature labor was examined in a population of low-income African-American women. The study augmented routine prenatal care with regular telephone contact by clinical nurse specialists to heighten the women's awareness of signs and symptoms of premature labor, thus facilitating early intervention. The inexpensive telephone calls made a difference. Only 6.7 percent of the women delivered low birth weight babies after receiving prenatal care

including the phone calls, whereas about 12 percent of the women who did not receive the phone calls with their prenatal care gave birth to low birth weight babies.

A second study is exploring the health care needs of Hawaiian, Japanese, and Filipino pregnant women living in a rural, low-income district of Hawaii, who frequently avoid prenatal care until late in pregnancy. After discovering several factors related to this delay, the researchers worked with public health nurses to design a culturally-sensitive prenatal care program. With community peers and native healers, who help form community support systems, women are being identified early in pregnancy to receive prenatal care. The ultimate goal of this study is to design a culturally-specific prenatal program to ensure maternal health and prevent low birth weight babies.

SUCCESS RATES

Question. What is the success rate for the NINR and for NIH as a whole? Why is the success rate for NINR so much lower? And what can be done to correct this difference in fiscal year 1995 and beyond?

Answer. The success rate for the NINR under the fiscal year 1995 President's Budget is estimated to be 12.2 percent; the estimate for NIH overall is 27 percent. The reasons for the widening gap between NINR's success rate and the NIH average have been explored, and it appears that the problem is primarily attributable to the small base on which percentage increases are applied as well as a higher, although stabilizing number of high-quality applications. The NIH recognizes the problems inherent in working with such a small base and is concerned about this issue. Obviously the most efficient strategy would be somewhat larger increases for NINR over the next few years to gradually bring the Institute into an appropriate balance with other ICD's; however, we are clearly facing a period of limited resources. Acknowledging the unique contributions that the NINR can and has made in collaborative efforts with other ICD's, it is recommended that the NINR continue to leverage resources with the other Institutes until NIH is confronted with less constrained financial conditions.

HEALTH CARE REFORM

Question. What is NINR doing to provide practice knowledge for community-based care focused on health promotion and disease prevention, as emphasized under health care reform?

Answer. Health care reform calls for prevention strategies and an increase in community-based care. Both of these will be a focus of a NINR initiative in fiscal year 1995 as we implement the next priority of the National Nursing Research Agenda. This initiative will expand the NINR research portfolio to include studies on community-based health care models targeted to primary health care intervention strategies for vulnerable and underserved populations in rural and inner cities. Particular emphases of the first part of this initiative which will be implemented in fiscal year 1995 will include health promotion, disease prevention, continuity of care, means of obtaining care, and costs of care. The goal will be to test models that have the potential of achieving culturally sensitive quality clinical health care services for these at-risk populations in a cost effective manner.

This initiative builds on a number of studies currently supported by NINR. Approximately 45 percent of the NINR research portfolio is directed at health promotion/disease prevention with particular emphases on child and adolescent health, reproductive health, elderly health, and chronic and recurrent health conditions. Examples of these studies include a successful program to increase colo-rectal cancer screening in socioeconomically disadvantaged, poorly educated elderly in community meal sites. Early cancer screening is a fruitful prevention strategy because an estimated \$8 is saved in treatment costs and lost earnings for every dollar spent on early detection of cancer. Another study focused on the prevention of cardiovascular disease in high-risk rural children. Using a nurse-designed educational program taught by classroom teachers, these children experienced a significant drop in cholesterol levels and measurements of body fat. In addition, the children's knowledge about basic cardiovascular principles, exercise, smoking, and nutrition improved significantly after the classroom instruction.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

STATEMENT OF ENOCH GORDIS, M.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Gordis, Director of the National Institute on Alcohol Abuse and Alcoholism.

Dr. GORDIS. Thank you very much, Mr. Chairman. In the interest of time I will try to make my remarks brief.

Our mission at the National Institute on Alcohol Abuse and Alcoholism is to conduct scientific research that would help us prevent alcohol problems before they occur and treat them more effectively once they do. I think the addictions represent an area which illustrates the fact that the border between behavior and biology is rapidly disappearing, because everything we do in molecular biology and in neuroscience really is a study of its impact on behavior.

One of the questions that we seek to answer, of course, is why only a fraction of people who begin to drink get into trouble from it. For that reason, we have a major study going on in genetics now in six centers to find the genes which confer that portion of the vulnerability to alcohol abuse and alcoholism which is inherited. Expansion of our budget of course would permit us to enlarge the study of this area of genetic vulnerability in many ways which time does not permit me to enumerate.

Another important area is neuroscience. We are interested in the relation of alcohol to the receptors in the brain, and the impact of this relationship to receptors on all aspects of alcoholism: the hunger for the drug, withdrawal from it, and brain damage. For that purpose, with the moneys that are proposed we would enlarge our activities to include imaging studies of the craving for alcohol and the motivation to drink. These studies are on the threshold, I think, of a new era.

Treatment also has been changing rapidly in the last few years. Not only are we analyzing rigorously the kind of treatments which have been done for the last few decades, but there is a new promise of potent pharmacotherapy for craving. The development of these medications will have an immense effect on the treatment of alcoholism and the cost saving that will ensue from this. Time does not permit me to expand on these.

PREPARED STATEMENT

In relation to the question of the FTE's I wish to underscore that what has been said before is absolutely true: It is not just individuals, it is programs that go with FTE's. This is especially acute for the three former ADAMHA Institutes, which have been mandated to spend 15 percent of their budgets on health services research. As you can see, the combination of that requirement, which we are

doing our best to accomplish, together with the FTE reductions has a major impact on our programs.

With that, I think I will stop here.

[The statement follows:]

STATEMENT OF DR. ENOCH GORDIS

Mr. Chairman and members of the subcommittee, I am pleased to be here with you today to discuss the research advances and fiscal year 1995 program directions of the National Institute on Alcohol Abuse and Alcoholism, the Nation's preeminent Federal organization for biomedical and behavioral research to reduce alcohol morbidity and mortality. Our most recent and exciting discoveries I will highlight shortly.

Alcohol is a legal drug used by more Americans than any other drug, including tobacco, and is the Nation's number one drug of abuse. It accounts for more economic and social damage than all illegal drugs costing the Nation \$98.6 billion each year. More than any illegal drug, alcohol injures the human body pervasively. However, through our research and research dissemination activities, the nation is becoming increasingly aware of the dangers of excessive alcohol use for the individual, the family, and society.

The core of the scientific enterprise is basic research. Science seeks to uncover elemental knowledge of the human body—and the nature of disease—to enhance our ability to treat and prevent disease. Specifically at NIAAA, our basic research program is comprised of studies that include the body's major organ systems, as well as studies that run the spectrum of the human life cycle—from the fetus to the elderly. Studies in genetics, the nervous system, cellular and molecular biology, and immunology are conducted by our extramural and intramural scientists. NIAAA's unique role and contribution to the Nation's basic research effort is determining the pathological effect on cells, neurons, and genes of the abuse of and addiction to alcohol. A prime example of the fruits of our basic research is our discovery in the 1970's of Fetal Alcohol Syndrome [FAS].

NIAAA complements its basic research program with behavioral and epidemiologic research and addresses the crucial questions on the causes, diagnosis, consequences, treatment and prevention of alcohol abuse and alcoholism. The results of NIAAA research have directly contributed to improved health for the population; decreased costs to society; and achievement of national goals.

NIAAA researchers have now shown that genetics plays a major role in the familial transmission of alcoholism in women, just as it does in men. This advance will help us design new treatment and prevention strategies for women. Earlier research was inconclusive about the genetic influence on women.

In the area of medications development we have good news to report. Two recent clinical trials have shown particularly promising results in treating alcoholics with naltrexone, an opiate antagonist. It was very effective in reducing alcohol craving, alcohol consumption, and relapse. These results are very encouraging. Future advances in understanding brain chemistry and physiology will provide new pharmacotherapeutic possibilities for the treatment of dependent individuals.

The development of medications for the treatment of cirrhosis and alcohol-induced hypertension is also on the horizon. NIAAA research has revealed that alcohol is the direct toxin in alcoholic liver disease and that a specific form of collagen is associated with the risk of cirrhosis—the ninth leading cause of death in the country. The possibility now exists that medications can be developed to reduce or even reverse fibrosis of the liver. With regard to hypertension, our intramural researchers have recently discovered that alcohol inhibits a cardiovascular reflex by increasing the activity of a neurotransmitter known as GABA. We are optimistic that this knowledge is the first step toward medications to counteract the effects of alcohol on blood pressure.

In the area of prevention, alcohol-related traffic fatalities remain the number one cause of death for youth, but I am happy to say that NIAAA studies have reported that legislation that raised the minimum drinking age to 21—of which NIAAA research provided the scientific basis—dramatically reduced alcohol-related driving deaths, especially among persons 16 to 20 years of age.

An increase during the past several years in new techniques and technologies for brain imaging now enables unprecedented examination of the nature and mechanisms of the brains of FAS children. Studies have revealed fairly consistent alterations in the basal ganglia, a region that controls some of the behaviors affected by alcohol exposure. This provides us with new insight into the mechanisms of the

central nervous system, and may lead to more sensitive diagnostic tools to detect cognitive deficits due to fetal alcohol exposure.

In fiscal year 1995 under the President's request, NIAAA is focusing its research efforts on areas that target special populations as well as the population as a whole. These areas are: women's health, medications development, health services research, minority health, youth, and prevention. These research areas have a critical need for new knowledge and great potential for significant advances. There is mounting evidence that women who abuse alcohol also have a greater risk than men of developing cardiovascular disease, hemorrhagic stroke, reproductive and endocrine anomalies, and breast cancer. The Institute will expand its current research on alcohol's role in these diseases as well as investigating the mechanisms of increased vulnerability. NIAAA will also continue to support the largest and most in-depth longitudinal study of women's drinking ever conducted in the United States. Data from this study will provide information on the dynamics of women's drinking.

As alluded to previously, research on medications development to treat craving, withdrawal, and relapse; and alcoholic liver and other alcohol-related diseases are extremely promising and will receive continued high priority.

The impact of alcohol abuse and alcoholism on children and youth is profound. There are direct and lasting effects of FAS on afflicted children; and the possibility exists that alcohol dramatically affects the physiological, social, and interpersonal development of youth during adolescence. These are topics that need further research. NIAAA is investigating the cellular and molecular mechanisms contributing to FAS; and the effects of alcohol on normal hormonal activation during puberty, as well as the development of gender differences in behavior and physiology.

Health Services Research, an emerging area within alcohol research, focuses on evaluating the effectiveness and efficiency of prevention and treatment approaches for alcohol problems as they are implemented in real world settings. In our efforts fully to develop this area, NIAAA has organized its health services research activities into four areas: financing and reimbursement of services; effectiveness of services and client/patient outcomes; service utilization and costs; and delivery system organization and management. Our expertise on these issues contributed in part to the administration's health care reform proposal.

Prevention research at NIAAA seeks to determine the family, socio-cultural, legal, and other environmental triggers that can interact with individual vulnerability and result in alcohol abuse and alcoholism. Advances in study designs make increasingly precise evaluations of interventions possible. Research on the economic influences that affect decisions to drink; the relationship of alcohol and violence, alcohol-related injuries; and FAS prevention efforts are receiving our continued support.

NIAAA-supported researchers are exploring alcohol problems in minorities and are striving to discover the genetic and environmental factors that place them at risk or protect them from alcohol problems. Some minority groups such as African Americans and Native Americans exhibit a higher prevalence of alcohol-related problems than Whites despite similar or lower rates of consumption. Areas of research that will be expanded are studies that will determine special treatment needs that may exist for minority communities; and studies that explore unique genetic, socio-cultural and environmental factors that increase or decrease the risk of alcoholism and related pathologies.

In closing, alcohol abuse and alcoholism have constituted major problems for humanity throughout history. Only in recent times has there been a concerted effort by science to discover the causes and develop effective treatment approaches and prevention measures. With the continued, committed efforts of alcohol researchers and our Institute, I am very optimistic that our future expectations to reduce the suffering of millions of people, and the associated economic and social costs of this severe public health problem will be realized.

Mr. Chairman, the fiscal year 1995 request for NIAAA is \$182,498,000, excluding AIDS. I will be pleased to answer any questions that you may have.

BIOGRAPHICAL SKETCH OF DR. ENOCH GORDIS

Enoch Gordis, M.D., became the Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in October 1986. Prior to this, he was Professor of Clinical Medicine at Mt. Sinai School of Medicine, New York City, and a staff member of the Elmhurst Hospital in Elmhurst, N.Y., where he directed the hospital's alcoholism program from 1971 until his appointment to NIAAA.

Dr. Gordis received his M.D. degree from Columbia University in 1954, and trained in internal medicine at the Mount Sinai Hospital in New York. During this period, he also was a research fellow in Dr. Solomon Berson's laboratory at the

Bronx Veterans Administration hospital. Following his residency, Dr. Gordis spent 10 years at New York City's Rockefeller University in the laboratory of Dr. Vincent Dole, conducting research in the areas of lipid metabolism, toxicology of carbon tetrachloride, analytical biochemistry of drug stereoisomers, the metabolism of alcohol and alcohol withdrawal. Subsequent to his tenure with Dr. Dole, Dr. Gordis founded the alcohol treatment program at the City Hospital Center at Elmhurst, New York, a large, comprehensive program with both inpatient and outpatient components serving some 15,000 patients during his tenure, and was Professor of Medicine at Mount Sinai School of Medicine. He has published on the clinical evaluation of alcoholism treatment, biological markers of drinking, disulfiram therapy, and the relationship between science and social policy.

As NIAAA Director, Dr. Gordis' principal goal is to continue support for activities designed to give maximum visibility to the Institute's role as a leader in alcohol-related research and the integral part of that role in preventing and treating alcohol abuse and alcoholism. This will include continued support for NIAAA's extramural and intramural research programs; support for a continuing Institute role in health professional education; increased attention to public policy research; and enhanced data collection and dissemination activities. The current NIAAA budget is \$176.5 million.

A member of Phi Beta Kappa, Dr. Gordis received his B.A. degree from Columbia University in 1950 and M.D. degree from the Columbia College of Physicians and Surgeons in 1954. He is a member of the Institute of Medicine of the National Academy of Sciences, the American Physiological Society, the American Federation for Clinical Research, Sigma Xi, the American Gastroenterological Association, and Fellow of the American College of Physicians.

QUESTION SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTION SUBMITTED BY THE SUBCOMMITTEE

NIAAA ACTIVITIES REGARDING ALCOHOL AND YOUTH IN RURAL AREAS

Question. In its fiscal year 1994 Committee Report, the Senate directed your Institute to establish a family-focused research program that will identify early precursors of alcohol problems during childhood and adolescence in rural areas.

Please detail your Institute's response to that directive.

Answer. NIAAA is currently involved in various research activities related to alcohol and youth in rural settings, including a number of grants and a technical review. In October 1993, the NIAAA issued a Request For Applications on Alcohol and Minorities: Biomedical and Behavioral Research, which encourages grant applications involving rural populations. Applications received under this announcement will be evaluated under the Institute's peer review process and will be submitted to the National Advisory Council in September. The Institute's Request For Applications on Alcohol and Youth also elicited grant applications which are relevant to rural populations. The Institute plans to make grant awards based upon scientific merit for alcohol and youth in rural settings.

The NIAAA currently supports a variety of grants relating to alcohol use and alcohol-related problems among youth in rural settings. Four grants directly address alcohol use and related problems among youth in rural areas. Two additional grants address Native American populations who seem to be disproportionately affected by alcohol abuse and alcoholism. One studies youth and their families; one is collecting retrospective data from adults to identify risk factors. The Institute will contribute to a technical review on this topic April 26 and 27 of this year in Washington, D.C., resulting in a monograph, which should stimulate increased interest in the alcohol abuse problems of rural youth. Additionally, NIAAA staff are continuing to encourage research in this area through informal contacts with investigators in the field.

NATIONAL INSTITUTE ON DRUG ABUSE
STATEMENT OF ALAN I. LESHNER, Ph.D., DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Leshner, Director, National Institute on Drug Abuse.

Dr. LESHNER. Well, it is a pleasure to be the cleanup. [Laughter.]

I want to say that the prospect of a 50-percent increase comes at a particularly opportune time, not only because I am a new Institute Director, but, also because the science of drug abuse and addiction has really seen some truly phenomenal advances in the last 3 or 4 years. Those opportunities provide truly unique and exciting opportunities for us as a country to significantly improve drug abuse prevention and treatment approaches.

Those opportunities come in basic science, in clinical science, and across the very broad array of disciplines that we try to bring to bear on this very complex social and medical problem. For the sake of time, I am going to restrict myself to just three examples, but I will submit some more for the record.

Probably the most astounding fact that I could give you about the science of drug abuse is that in the last 3 or 4 years NIDA-supported researchers have identified and genetically specified the molecular receptors in the brain for every major drug of abuse used in this country. These discoveries make it at last possible for us to begin a rational medication development strategy that will allow us to develop far more effective treatments for drug abuse.

We have treatments that work. Everybody knows that. Drug abuse treatment can work. However, drug abuse treatment takes an extremely long period of time, it is very inefficient, and it does not work for a large number of people.

The Institute of Medicine yesterday released a report on drug abuse medication development, which called for a significant expansion in that strategy and pointed out, as Dr. Varmus pointed out earlier this morning, that basic science is going to have to be the base from which we move in order to develop more effective treatments in the future.

The second point I would make is that drug abuse will continue to fuel the AIDS epidemic until and unless we can take the necessary steps to improve both prevention and treatment. Almost a third of AIDS cases are directly attributed to drug abuse or are drug abuse-related.

Drug abuse treatment does work in the prevention of AIDS, and our treatment improvement program is probably our major contribution to AIDS prevention. However, I would also point out that, contrary to popular belief, our outreach and prevention programs have shown that you can reach drug abusers and you can change their behavior. We are now beginning to see some systematic

changes in the use of unsafe needle practices and some changes in unsafe sex practices. So we see some progress on the horizon.

The last point that I would want to make is to emphasize what I believe to be one of the major tragedies of drug abuse, and that is its effects on children. Babies born to addict parents suffer medically. Children raised in drug abusing households suffer emotionally. And adolescents who abuse drugs suffer the risk of ruining their lives.

PREPARED STATEMENT

Studying the effects of drug abuse from infancy through adolescence, including prevention strategies and treatment strategies, is going to be a major NIDA priority, and we would be happy to have the resources to do it.

Thank you.

[The statement follows:]

STATEMENT OF ALAN I. LESHNER, PH.D.

Mr. Chairman and members of the subcommittee, I am pleased to come before you as Director of this superb NIH Institute and to review some of our accomplishments and plans. NIDA sees its principal mission as bringing the full power of science to bear on what to many believe is our Nation's most pressing public health and social problem, drug abuse and addiction. We then take that scientific information and work to ensure its rapid application in both real-life medical practice and health policy settings.

NIDA was created in 1974 with the conviction that drug addiction, like cancer and heart disease, is a complex illness that can be addressed by scientific research. This approach has allowed us to make some truly exceptional advances in understanding, treating and preventing drug addiction. The accomplishments of the past decade, and especially the past few years have been nothing short of extraordinary and these accomplishments form the basis for our expectations for accelerated progress in addressing the problems of drug abuse. For example:

- We have now identified and genetically specified the molecular sites in the brain where every major drug of abuse has its initial effect. These discoveries, together with computer-aided drug design, should enable us to rapidly synthesize novel compounds to break the cycle of addiction.
- We have identified endogenous opiate systems in the brain that are involved in addiction, pain, and other diseases and physiological functions.
- We have identified the brain receptors for the active ingredient in marijuana, Δ^9 -tetrahydrocannabinol, and have discovered endogenous brain chemicals that act on these receptors.
- We worked to develop methods and standardized procedures for analyzing urine, hair, and meconium for signs of drug exposure. These technologies are invaluable in workplace drug prevention programs and for forensic purposes.
- We defined the addictive nature of nicotine, its similarities to cocaine, and the role that cigarette smoking plays as a risk factor for drug abuse.
- We have also enhanced our abilities to treat drug exposed children, measure the extent of drug abuse in various populations, treat cocaine abuse using behavioral techniques, measure the abuse potential of new drugs, specify the neurotoxicological effects of drugs, and use methadone and other interventions to help prevent HIV.

NIDA researchers also continue to investigate the prevalence of drug abuse among our children through our annual survey of high school students. Drug abuse can destroy the lives of children and adolescents and our recent surveys indicate that this problem is not going away. Our studies have confirmed the common sense view that as the perceived risk of using drugs goes up, the use of drugs goes down; that was the pattern for most of the past decade. Unfortunately, the most recent data show that the perceived risk has decreased and use has increased. These findings raise concern and reinforce the notion that we must continue to provide information about the risks of drug use and learn how to further emphasize the social norms that oppose drug use.

A particularly exciting accomplishment for NIDA during 1993 was the approval of a new medication for the treatment of heroin addiction. LAAM, 1-alpha-acetyl

methadone, is the first new medication for the treatment of heroin since methadone was approved over 20 years ago. LAAM's main advantages are that it has a long duration of action and needs to be administered only three times per week, thereby reducing clinic visits, and it appears to have limited abuse liability, thereby cutting down on illicit diversion.

NIDA is moving forward with a number of new and exciting medications for drug addiction. We recently completed safety studies of a long acting form of the opiate antagonist naltrexone. This dosage form can provide up to 30 days of opiate blockade, preventing heroin abuse during this period. Additional medications under development for opiate addiction include buprenorphine, which combines the best attributes of methadone and naltrexone in a single medicine, and other compounds that will make it easier to medically withdraw addicts from drugs.

NIDA is also supporting efforts to develop medications to treat cocaine and crack abuse. With the recent cloning of the gene for the dopamine transporter, one of the prime brain sites at which cocaine acts, the time is ripe to develop medications that can block the action of cocaine. This will be a daunting task but scientists at NIDA's intramural research program at the Addiction Research Center have identified some novel compounds that, hopefully, will inhibit the action of cocaine on the brain reward system without destroying the ability of an individual to experience drug free natural pleasures.

NIDA research has demonstrated that treatment can work. However, we need to improve techniques to recruit and retain patients in treatment and prevent relapse. We are also finding that multi-component preventive programs, such as school-based interventions, supported by parent education and community-wide media campaigns, are more likely to be effective in reducing drug use, compared to more limited approaches. Additional research is needed to identify protective factors such as effective parenting.

Through its National AIDS Demonstration Research Program, NIDA is also demonstrating that outreach programs can significantly alter behaviors associated with the spread of AIDS associated with drug use. This program is also determining the most effective interventions in different communities.

These discoveries, and those of the past two decades, have provided us with unprecedented insights into, and new technologies to study, the actions of drugs in the brain and the cascade of events which contribute to addictive behavior. It is critical that we build on these findings by continuing to support, and indeed expand support, for research in promising areas.

New technologies have provided us with a realistic view of the brain mechanisms underlying drug reward and euphoria. Ten years ago our understanding of the brain circuitry involved in reward could be represented by a simple cartoon. A diagrammatic representation of our current understanding of the brain's reward system shows a highly complex series of brain areas and neuronal interconnections. Advanced techniques, such as the capability to simultaneously study the activity of several hundred neurons, are also allowing us to gain new insights into how individual neurons in these areas are involved in addiction. This has already provided a comprehensive view of neural activity in the brain reward system related to drug self-administration. This more realistic view of the brain will ultimately help us develop more realistic approaches to prevention and treatment.

It is clear that molecular biology and neuroscience are two of the most exciting areas of drug abuse research in which NIDA needs to expand support to take advantage of recent advances. The cloning of the genes for the receptors for each of the major drugs of abuse, for example, provokes new questions and new thinking about drug actions and brain function. Specifying the location of these genes as part of the Human Genome Project, determining specific biological vulnerabilities of drug addiction, and the possibility of gene-based therapies for drug addiction are but a few of the exciting opportunities.

The complex relationship between behavior and biology in drug use can also be more fully explored using advanced technologies, such as neuroimaging. For example, new techniques can monitor the neuropsychological status of an awake subject while viewing a computerized image of the brain. Such technologies may dramatically increase our understanding of the biological bases of craving, drug-seeking behavior, euphoria, drug tolerance, drug dependence, and drug addiction, and should be extremely useful for the development of effective therapies. These technologies will also allow us to determine whether pharmacological and/or behavioral interventions will reverse neurobiological and neurochemical changes caused by drug use. Such changes show that even after three months of cocaine abstinence, the brain of a former cocaine addict is still functioning abnormally.

We also anticipate substantial progress in the development and refinement of psychosocial and behavioral therapies for the treatment of drug addiction. NIDA is

launching the Behavioral Therapies Development Program which will build upon knowledge gained from basic behavioral and clinical studies to define, develop, and refine behavioral therapies, including behavioral interventions, psychotherapies, counseling approaches, and other rehabilitative strategies.

NIDA's health services research program also promises opportunities for important progress. NIDA views research on drug abuse treatment and prevention services, the linkage between drug abuse and the primary health care system, and HIV/AIDS prevention services research as major components of our research program. This comprehensive, multidisciplinary approach to drug abuse health services research is necessary because of the unique characteristics of drug abuse clients, the range of needs they present, the changes in health care organization, financing, and utilization which are taking place, and the need to understand how and why some clients respond to prevention and treatment while others are resistant to engagement and change. Future health services research will build on the existing knowledge base and focus on areas relevant to prospective changes in health care organization, financing, and utilization.

NIDA will continue to support research in other areas as well, including studies to develop integrated and comprehensive pharmacologic and behavioral treatments; studies of the effectiveness of prevention programs; investigation of the natural history of drug abuse and its consequences, including diseases associated with drug abuse, such as AIDS and tuberculosis; clarification of behavioral issues that impact getting drug users into treatment, retaining them there, and preventing relapse; and studies of the developmental problems which may result from maternal drug use. Equally important are efforts to expedite the transfer of information between providers and researchers.

Mr. Chairman and members of the committee, the rapid advances made in the fields of neuroscience, molecular biology, and sophisticated behavioral science research together with the many accomplishments in other areas of drug abuse research, now provide us with a base from which to take advantage of unparalleled opportunities to address the problems of drug abuse. We have an opportunity to improve primary health care, reduce infant mortality, promote mental health, advance health care for women and minorities and the underserved, and prevent and treat HIV infection and tuberculosis through drug abuse research. NIDA's overall objective is to improve our understanding of drug abuse and related problems and to develop more effective interventions. We must continue our present research efforts and, in line with the President's budget, we should expand our efforts in the several most promising areas I have noted.

Thank you Mr. Chairman. I would be pleased to answer any questions.

BIOGRAPHICAL SKETCH OF ALAN I. LESHNER, PH.D.

Dr. Leshner was appointed Director of the National Institute on Drug Abuse in February 1994. Prior to that appointment, he served as Deputy Director of the National Institute of Mental Health since 1988, where he also served as Acting Director from 1990 to 1992.

Among his accomplishments have been a major restructuring of the priorities and programs of the National Institute on Mental Health to greatly enhance treatment research, a set of programs to build the mental health field's clinical research infrastructure, and strategic plans to advance health services research. He also has provided leadership in the development of major national resources, like the Human Brain Project, and in articulating and developing the basic neuroscience and behavioral science portfolios of NIMH. He was appointed by the Secretaries of HHS and HUD as Chair of the task force that produced Outcasts on Main Street, which lays out a blueprint for substantially reforming the national system of care for homeless persons with severe mental illnesses and substance abuse, and he was involved in the President's Health Care Reform Task Force.

Previous to his work at NIDA and NIMH, Dr. Leshner held a broad variety of positions at the National Science Foundation [NSF]. He was Director of the Office of Science and Technology Centers Development, responsible for a Foundation-wide program to develop and support major research centers around the country across all fields of science and technology. Before assuming that position, Dr. Leshner had been deputy to the NSF Assistant Director for Biological, Behavioral and Social Sciences. He served in numerous other positions at NSF, including overseeing the National Science Board [NSB] Commission on Precollege Education in Mathematics, Science and Technology, one of the two national commissions of the early 1980's that brought renewed attention to the nation's severe problems in elementary and secondary education.

Dr. Leshner went to NSF after 10 years at Bucknell University where he was Professor of Psychology. While on the faculty at Bucknell, he also held long-term visiting appointments at the Postgraduate Medical School in Budapest, Hungary, at the Wisconsin Regional Primate Research Center of the University of Wisconsin, and as a Fulbright Scholar at the Weizmann Institute of Science in Israel. Dr. Leshner's research has focused on the biological bases of behavior. His laboratory's work emphasized the role of peptide and hormone effects on appetitive behavior, motivation, learning and memory, and such social behaviors as aggression and submission. He is the author of a major text on the relationship between hormones and behavior, *An Introduction to Behavioral Endocrinology*, and numerous book chapters and papers in professional journals. He also has published extensively in the areas of science and technology policy and education.

Dr. Leshner received his undergraduate degree in psychology from Franklin and Marshall College, and the M.S. and Ph.D. degrees in physiological psychology from Rutgers University. He has been elected a Fellow of the American Association for the Advancement of Science, the American Psychological Association, the American Psychological Society, and the New York Academy of Sciences. He has received awards for his national leadership from such diverse groups as the American Psychiatric Association, the National Alliance for the Mentally Ill, the American Psychological Association, the American Academy of Child and Adolescent Psychiatry, the National Mental Health Association, and the National Prevention Coalition.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you, Dr. Leshner.

For each Director I just asked, please provide the details and numbers for the record for both questions. I would appreciate that.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RURAL SUBSTANCE ABUSE

Question. In its fiscal year 1994 Committee report, the Senate directed NIDA to expand its research on substance abuse problems in rural areas. Please describe your Institute's response to this language, and outline what NIDA intends to do in fiscal year 1995 regarding substance abuse problems in rural areas.

Answer. Substance abuse in rural communities is a serious problem. Between 1988 and 1992 the rate of current illicit drug use in large metropolitan areas dropped from 8.9 percent to 6 percent, while the rate remained virtually unchanged in nonmetropolitan areas—5.8 percent in 1980 and 5.3 percent in 1992.

NIDA supports a significant program of research on substance abuse in rural communities. In fiscal year 1993, NIDA supported 11 individual studies for a total expenditure of \$5.6 million. One study at Iowa State, for example, focused on improvement of parent-child relationships among high-risk families in economically deprived rural areas. Previous efforts resulted in the development of a family risk prevention program called "Preparing for the Drug Free Years." Components include teaching family members skills for conflict resolution and for coping with stress, which are potential forerunners of adolescent substance use. Data suggest that the program can lower initiation rates on cigarettes by one-third, alcohol by two-thirds, and marijuana by half.

Though studies conducted in the past have contributed knowledge about drug use by rural Americans, there is now a need for longitudinal studies. This year NIDA will begin a comprehensive program of epidemiologic research in rural communities is planned in conjunction with the Department of Agriculture [USDA]. Objectives of this program are to establish effective monitoring and assessment of drug use patterns and trends in rural settings and among hard-to-reach populations residing in comparatively remote areas. Development of indicators of drug use and related disorders among hard-to-reach and vulnerable populations in rural environments for whom little systematic or comprehensive data are available would provide baseline measurement of drug use and allow for assessment of trends and identification of emerging substances of abuse. As part of this effort, NIDA plans to include a rural

substance abuse focus in nine State Epidemiology Work Groups that will be organized by NIDA over the next two and a half years.

Federal support for etiologic and prevention research on substance abuse in rural America is important. There is still much we do not know about illicit drug use in rural communities. Additional research is needed to find out what factors protect youth in certain communities and what factors make other rural youth vulnerable to drugs. Particular areas in need of investigation include: (1) variations on the role that information sources, residential environments, and prevention programs play as interrupting or facilitating influences on drug use; (2) supply-distribution sources in rural areas; and (3) relationship between ethnicity/race and drug use. NIDA has planned a technical review on what we currently know about substance abuse in rural areas, including information on epidemiology, etiology, and consequences, as well as prevention intervention models and service delivery. Based on the outcome of the review, NIDA will seek applications for fiscal year 1995 funding for a combination of epidemiology and prevention research projects.

DRUG ABUSE AND HIV/AIDS

Question. Please describe the AIDS-related research done at your Institute.

Answer. NIDA has built a comprehensive AIDS research program, including studies of the effects of drug abuse on the immune system; epidemiologic studies of seroprevalence and progression to disease among drug users, their sexual partners, and their children; and studies to assess prevention and treatment strategies to reduce behaviors linked to the transmission of HIV and progression to AIDS and associated diseases.

The AIDS epidemic continues to take an increasing toll among drug abusers and their families. In the United States, drug abuse is the second leading risk factor in adults for acquiring HIV, largely through the sharing of needles and through sexual contact with infected drug users. Drug abuse is the primary risk factor in infants and children, through mothers who are HIV infected as a result of their own or their sexual partner's drug use. One-third of AIDS cases are among injecting drug users [IDU's] or those who have had sex with IDU's. Data on racial and ethnic minorities indicate an overrepresentation of Blacks and Hispanics among IDU's with AIDS. HIV infection is not limited to drug abusers who inject drugs, but has also been spreading among other substance abusers through sexual transmission. A survey of five cities indicated an 11 percent HIV infection rate among heterosexual crack cocaine users who had never injected drugs.

NIDA provides national leadership on community-based HIV/AIDS behavioral and social science prevention research studies of drug abusers by supporting a research infrastructure that permits the conduct of: (1) efficacy trials of community-based interventions targeted to reducing HIV/AIDS risk-taking behaviors and preventing the spread of HIV infection; (2) HIV health services prevention research; and (3) qualitative, quantitative, other special research studies, and methodological investigations that are responsive to other urging HIV/AIDS and drug use research issues related to the prevention of HIV infection. Especially important are recent efforts to clarify the risks and benefits of harm reduction strategies such as needle/syringe exchange programs. Research has indicated that community-based street outreach programs are effective in recruiting hard-to-reach IDU's and crack smokers, facilitating behavior change, reducing needle and, to a lesser extent, sex risk behaviors, and influencing out-of-treatment users to seek drug treatment.

AIDS/HIV COMMUNITY-BASED OUTREACH

The overall goal of the AIDS community-based outreach/intervention research effort is to prevent the further spread of HIV infection among IDU's, their sexual partners, and those at demonstrable risk for initiating injecting behavior and those at risk of unprotected, frequent risky sexual behaviors associated with their use of crack cocaine. All 21 research sites use common research designs and protocols, eligibility criteria, a standard intervention, and pre- and post-intervention assessments. A major objective of the program is to support sero-epidemiological studies on out-of-treatment populations of IDU's, other drug users at high risk for HIV infection, and sexual partners of IDU's.

Through the community research program, NIDA will continue to promote and encourage research on: (1) social and behavioral change intervention research designed to reduce high-risk sexual practices among IDU's, crack smokers, and/or their sexual partners, (2) disinfection practices and on needle exchange programs focusing on ethnography, epidemiology and evaluation, and (3) comprehensive partner notification programs for sexual and needle sharing partners of seropositive drug users.

Drug abuse intervention can have a profound impact on reducing an individual's likelihood of HIV infection. In one study, every one of 641 IDU's on whom AIDS street outreach intervention research was performed reported sharing of non-disinfected injection equipment—needles, water, cottons—at the beginning of the study. After four years of direct intervention unsterile practices continued among only 14 percent of the group. The drop in high-risk injection practices resulted in the rate of new cases of HIV infection dropping from about 10 percent to about 2 percent annually. It is estimated there were only 90 seroconversions among the 641 subjects during the period—nearly 50 percent fewer cases of HIV infection than expected—as a result of the drop in use of non-disinfected injection equipment.

Future HIV prevention research efforts must build on past successes in reducing high risk injecting behaviors. Important areas of research include development of more effective interventions to reduce sexual risk behaviors in drug users to target IDU's who are resistant to risk reduction, to recruit high risk groups into treatment, to improve bleaching techniques among IDU's who continue to share needles, to assess alternative risk reduction strategies such as needle exchange, and to improve HIV testing and counseling approaches.

A study of HIV/AIDS among 465 IDU's in Los Angeles indicated that IDU's who continue to inject drugs while in methadone maintenance treatment share injection paraphernalia less than users not in treatment. IDU's in treatment have fewer sex partners than those not in treatment. Treatment influences sex-related HIV risk behavior by facilitating disengagement from paid sex and raising perceived self-efficacy for risk reduction. This suggests the need for further research that tests risk-behavior models that incorporate psychosocial, situational, and social-network factors. While many IDU's have adopted the use of bleach to reduce their HIV risk, data indicate that cleaning procedures are generally insufficient, suggesting the need for research on strategies for improving bleaching techniques and on alternate strategies to decrease shared needle use.

AIDS/HIV AND TUBERCULOSIS

Another facet of the AIDS epidemic is the re-emergence of tuberculosis [TB]. The reasons for this re-emergence are multiple and include a failing public health infrastructure in some districts, increased substance abuse, poverty, homelessness, and increasing HIV infection. NIDA-funded investigators have documented the effect of HIV-related immunosuppression on interpretation of tuberculin skin testing in a large cohort of IDU's. Data indicate that TB testing in HIV positive patients seriously underestimates the prevalence of infection. These findings have important public health implications since TB control is reliant on skin testing for identifying patients who should receive chemoprophylaxis. Other studies address the natural history of TB, co-infection with HIV, diagnosis, treatment adherence, and prevention of transmission. NIDA research also explores the impact of medications used to treat drug abuse as well as those used to treat AIDS and TB on the progression of HIV disease in drug users. Studies will compare progression rates and disease outcomes in such groups as active heroin users, abstinent drug injectors, and residents of drug-free therapeutic communities.

The effects of illicit drugs on the immune system continue to be studied through NIDA-funded research. Studies suggest that both opiates and delta-9-tetrahydrocannabinol [THC], the active ingredient of marijuana, can increase the adverse effects of some infectious agents. There is also evidence that morphine increases the pathogenesis of HIV-1 infection. Morphine amplifies the replication of HIV-1 in cell cultures activated with cytomegalovirus. There is also some evidence that nitrite inhalation decreases immune status.

In interviews with male IDU's who attended either a methadone clinic or an AIDS treatment clinic, personality and familial correlates of HIV risk were identified. Personality characteristics such as sensation seeking and impulsivity were related to HIV risk. Family strife was also related to risk behavior. These findings suggest that interventions with family members might be useful HIV risk reduction measures for further study.

NIDA research explores cultural factors that have an impact on female drug users and female sexual partners of IDU's, including research on the association between drug use, AIDS risk behavior and violence. A recent study of female prisoners indicated that women who have been victims of psychological trauma, particularly stemming from sexual abuse, abuse at an early age, and abuse by a family member, engaged in increased frequency and severity of AIDS risk behaviors.

INTERAGENCY COLLABORATIONS

NIDA exerts considerable effort to transfer research results to health professionals and community workers, and to develop new strategies for reaching teenagers and young adults about the problems of drug abuse, including innovative uses of media and materials working collaboratively with the Substance Abuse and Mental Health Services Administration to reach high-risk audiences and the general public, and these efforts will continue in fiscal year 1995.

NIDA staff are exploring the possibility of collaborating with NIAID on two large multi-site studies of HIV infection and AIDS to facilitate increased attention to drug abuse factors in women and pediatric populations. NIDA also collaborates with NIAID to assess the feasibility of including IDU's in clinical trials of candidate HIV preventive vaccines.

A joint announcement with the Substance Abuse and Mental Health Services Administration in the area of linkage of drug abuse treatment and primary medical care is close to being finalized. Another announcement is planned to highlight HIV prevention and treatment issues in drug abuse treatment programs, including issues unique to those who are already seropositive. Other special efforts that will continue in fiscal year 1995 include:

- Studies on the Medical and Health Consequences of Drug Abuse: Research on the role of drug abuse in the etiology and progression of medical, including psychiatric, disorders of drug abuse.
- Determinants of Effective HIV Counseling: Studies focusing on understanding the mechanisms determining the effectiveness of HIV counseling and testing activities.
- Health Care Services for Persons with HIV Infection: A joint program with NIMH, NIAAA and the Agency for Health Care Policy Research to promote short-term research to better inform decision makers developing public policy concerning delivery of health care services.

MEDICAL RESEARCH

Senator HARKIN. Again, let me thank you all for being concise and to the point. I may restructure this next year. I do not know. Maybe we have to split it up or something. I am very solicitous of your time. It is a great effort to get down here and I do not mean to impose upon that time. You have important jobs and your Institutes to run and the whole Institute in your case, Dr. Varmus.

But I do at some point want to get more in depth on some of these things than we have today.

Let me just close by saying that I hold each and every one of you in very high esteem, in very high regard. I have the utmost respect for each of you personally and professionally. You are in the vanguard of what I consider to be the most important research being done in America.

I am not alone in feeling that way. This poll to which I refer once in a while, the Harris Poll, was taken last fall, asked people in an open question what type of research they felt was most important to be funded in America; 66 percent said medical research. The next highest, environmental research, came in I think at around 12 percent. I may be off a little bit. I think the next highest was energy at 6 percent. Defense was like 4 percent, and no other form of research got over 1 percent.

So the American people want this type of research. They want to support you. For some reason there has been a disconnect between what the American people want and what we have been able to do.

I think that may be changing. I hope it is. I do not mean to get into any battles between life science and physical sciences. I used to chair the subcommittee that had jurisdiction of the National

Science Foundation and so I have a great deal of respect for the physical sciences also.

But I do believe that there is support out there for what Senator Hatfield and I and others are attempting to do, and I really believe we are going to get it accomplished in some form. I do not know what compromises will have to be made, but some form. I am hopeful that the view ahead is going to be much clearer and we are going to have the resources to do the types of things you elaborated on, albeit briefly, this morning, and I again would just close by saying that you have a lot of support among the American people. You are getting more support here in the Congress and we are going to translate that just mere verbiage to actual resources that you can use.

So with that, unless you have some closing remarks or anything else.

Dr. VARMUS. We are simply grateful for the chance to express ourselves. Thank you.

Senator HARKIN. I will submit for the record a number of specific questions for each of the Institutes and centers.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until 9:30 a.m., Tuesday, March 22, when we will meet in room SD-138 to hear from Secretary Riley of the Department of Education.

[Whereupon, at 1:07 p.m., Thursday, March 17, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 22.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1995

TUESDAY, MARCH 22, 1994

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, Murray, Specter, Hatfield, Stevens, and Cochran.

DEPARTMENT OF EDUCATION

SECRETARY OF EDUCATION

STATEMENT OF HON. RICHARD W. RILEY, SECRETARY
ACCOMPANIED BY MARSHALL S. SMITH, UNDER SECRETARY

OPENING REMARKS OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education will come to order.

Today is the second of three hearings with Cabinet secretaries within the jurisdiction of this subcommittee to discuss the fiscal 1995 budget.

It is indeed a pleasure once again to welcome Secretary Riley to the subcommittee to discuss the budget for next year for the Department of Education.

Secretary Riley has a long distinguished career as an advocate for education reform, first as Governor of South Carolina, and now in his current position at the Department of Education.

Following Secretary Riley's testimony, we will hear from a panel, including three of the Department's assistant secretaries, Mr. Tom Payzant, the Assistant Secretary for Elementary and Secondary Education; Augusta Kappner, Assistant Secretary for Vocational and Adult Education; and David Longanecker, Assistant Secretary for Postsecondary Education.

For more than a decade now, we have become increasingly aware that while there are many fine schools in States and communities across the land, overall, we are not doing the best job possible in providing the quality education our young people need to secure good jobs in our globally competitive economy. In response, Presi-

dent Clinton has made education a priority, and his administration has launched an ambitious reform agenda to upgrade the quality of education for all students in America's 85,000 public schools.

Secretary Riley, I want to congratulate you for your efforts on the President's behalf, especially for your work on critical education reform legislation, and especially your success last year in enacting the Student Loan Reform Act, which expanded the direct lending and greatly reduced the costs of the guaranteed student loan program. You will shortly be able to add the Goals 2000, the School-to-Work Opportunities Act, and the Safe Schools Act.

Of course, as pleased as I am with your success, I have to tell you that it only makes our jobs as appropriators even more difficult, because as hard as you worked to get this legislation passed, paying for it may well be an even bigger challenge, and that is what we are here to talk about today.

FUNDING EDUCATION'S REQUEST WITHIN BUDGET CAPS

For fiscal year 1995, the President is requesting \$26.1 billion in discretionary funding for the Department of Education, a net increase of \$1.7 billion, or 7 percent more than last year's level.

Most of this increase—in fact, \$1.5 billion of the \$1.7 billion—is for investment spending, which totals more than \$9 billion in the President's request. I will not go through all of those.

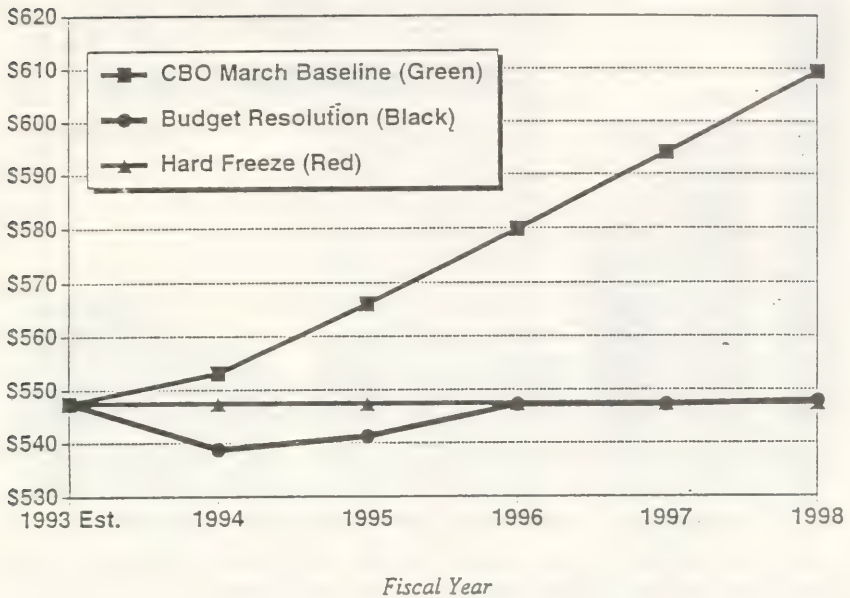
Mr. Secretary, this investment package includes a number of important and worthy programs. But I would be negligent if I failed to warn you and your colleagues in the Cabinet that the investment package that is at the heart of the President's budget is in jeopardy. The problem is the tight budget caps passed by Congress last year. And it is likely the budget squeeze is going to get even tighter.

RECONCILIATION BILL'S FREEZE ON DISCRETIONARY OUTLAYS

Before you begin, let me just briefly go over my charts, as I do with every Secretary. President Clinton, in his State of the Union address, said this will be one of the toughest budgets ever presented to Congress. Well, that is true. The first chart on my right highlights the source of this pressure.

Discretionary Outlays

(Dollars in Billions)



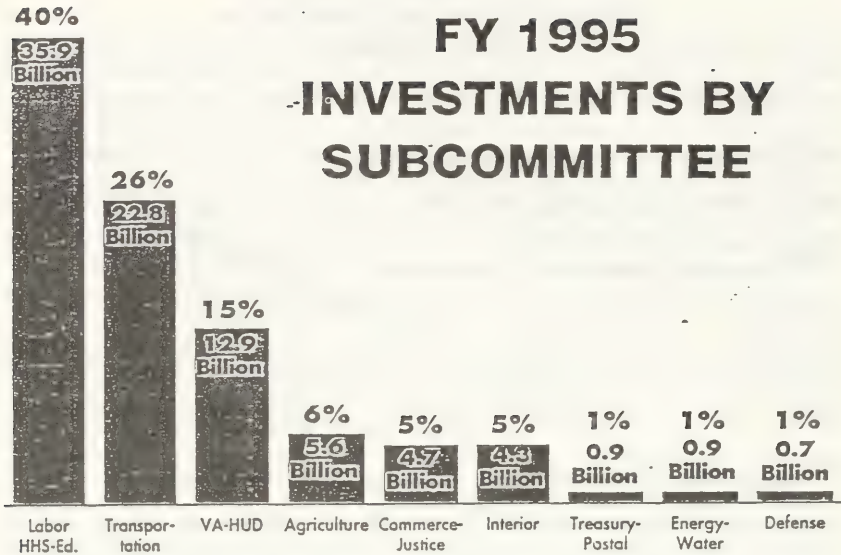
Last year's reconciliation bill essentially froze discretionary outlays for 5 years. Under these tight caps, discretionary spending for fiscal year 1998 will be the same as fiscal year 1993 levels, and \$62 billion below the CBO baseline. In other words, the baseline is the green line going up. The red line is the budget. And the black line is basically where we are right now. We are actually below the hard freeze.

So, that is one of our problems that we are confronting this year and will be in the future.

PRESIDENT'S INVESTMENT PROGRAMS BY SUBCOMMITTEE

Now, our subcommittee is not immune from these pressures. The next chart, going from your right to your left, the middle chart up there, shows the President's investment programs by subcommittee. As you can see on the far left, this subcommittee has the bulk of it—40 percent of all of the President's investment programs fall under the jurisdiction of this subcommittee.

FY 1995 INVESTMENTS BY SUBCOMMITTEE



PRESIDENT'S PROPOSED EDUCATIONAL INVESTMENTS

The third chart on the far left is basically the education investments and the total there, as you can see on those.

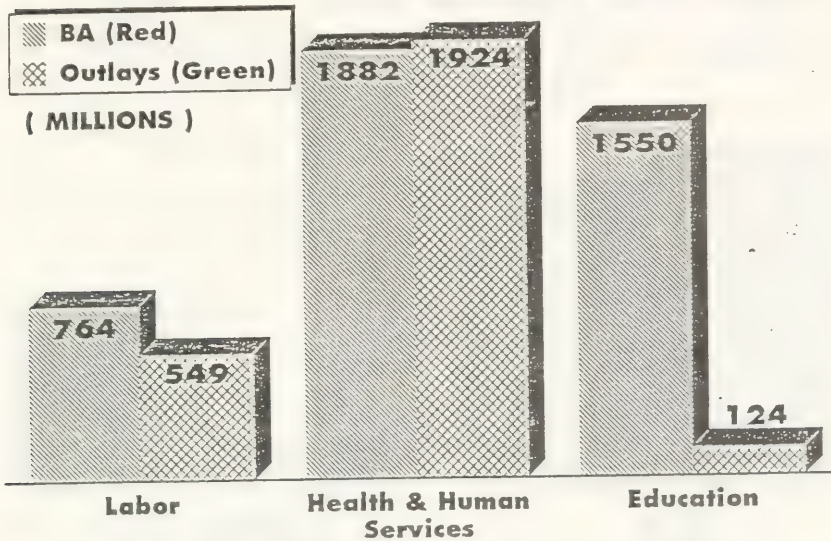
FISCAL YEAR 1995 EDUCATION INVESTMENTS

[In millions of dollars]

	Fiscal year 1995 estimate		Fiscal year 1995 versus fiscal year 1994	
	Budget authority	Outlays	Budget authority	Outlays
School-to-work	150	52	+ 100	+ 46
Goals 2000	700	154	+ 595	+ 141
Title I, education for the disadvantaged	7,579	6,918	+ 667	+ 29
Safe and drug-free schools	660	521	+ 188	- 92
Total, education	9,089	7,645	+ 1,550	+ 124

Over here on your far right, over there, is the breakdown by subcommittee. The increases over 1994—I can barely read them from here—which you can see, labor, health and human services, and education, you can see the budget authorities and the outlays—the increases over fiscal year 1994.

LABOR - HHS - EDUCATION INVESTMENT INCREASES OVER FY 1994



Now, as you can see in education, the budget authority is high and the outlays this year are low. But that budget authority increase is going to cause us some problems next year, too.

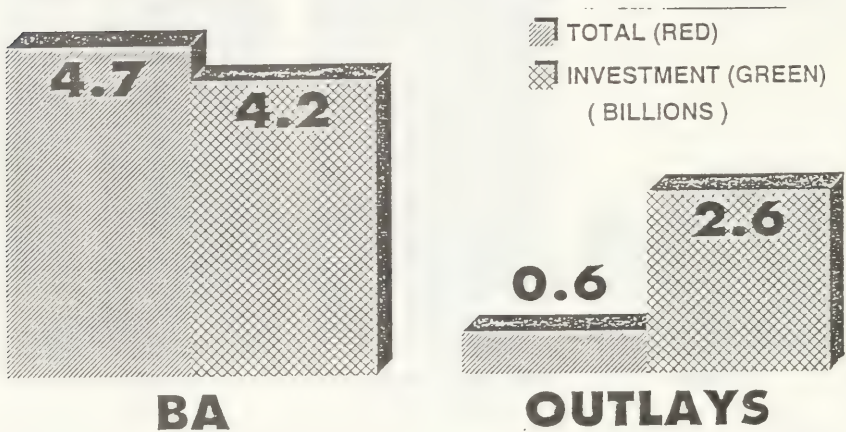
The center chart, showing total increases versus investment increases, really tells it all. In labor, health and human services, and education, this subcommittee, what that chart basically says is the total investment in budget authority is \$4.7 billion. In outlays, what we have is basically a 0.6 increase and 2.6 in outlays. So, if you subtract the 0.6 from the 2.6, we have about a \$2 billion shortfall.

IMPACT OF FUNDING INVESTMENTS WITHIN BUDGET CAPS

That is our problem. We have a \$2 billion shortfall. And that is what our problem is—where do we get the \$2 billion.

LABOR - HHS - EDUCATION INCREASES OVER FY 1994

Total Increases versus Investment Increases
(Discretionary BA and Outlays)



Source: Office of Management and Budget (OMB)

And, right now, what has happened is that in the President's budget, the investment package is financed with 33 program eliminations. Well, that saves \$639 million. But, again, these are programs that many times have been supported by various members of this subcommittee and other Senators and people in the other body. And so, I do not know how many of those are going to be cut or saved.

I might just also point out that last week the Senate Budget Committee reduced the caps by an additional \$43 billion over the next 5 years. And that is going to make it even tougher for us.

So, I do not know where we are going to get the extra \$1.3 billion that we are going to need for these investment programs. So, we are going to need to make sure that our allocation is high. Because, if we do not, then we are going to be, I think, robbing Peter to pay Paul, to use a well-worn cliché. We are going to be taking out of programs that are very supportive of education to try to find the investment money—which I agree with. I want to support those. I think it is the way we ought to go. But we really have this crunch on us.

So, I am concerned that this noose will strangle the programs that may not be investments for the President, but which are very important to many members of Congress and their constituents—and which maybe in some ways could be argued are part of investments also. I think you could argue that in many cases.

So, that \$2 billion gap is what we are concerned about. And we will do our best to try to meet the President's goals. I agree with

him. I have stated that to you privately and I do so publicly. To the maximum extent possible, this subcommittee will do everything it can to move in the direction of the President's investments programs. But I say that, again, with all caution, that with this \$2 billion gap, I just simply do not know how we are going to do it.

And any help and guidance you can give us on that, Mr. Secretary, I would sure appreciate it.

With that, I will turn to our ranking member, Senator Specter, for any opening comments.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman.

Mr. Secretary, I was about to join in welcoming you here. After the chairman's tough line, I am not so sure it is a welcome. There are so many problems that it is hard to be upbeat. We have a tough job ahead of us, and I know we can count on your cooperation and you can count on ours.

SUBCOMMITTEE ALLOCATION

There are a few specific items I want to discuss with you very briefly in this opening statement. At the outset, I would ask your assistance in our lobbying efforts to increase the allocation to this subcommittee, because we have tremendous responsibilities. The LIHEAP program, assistance to low-income people for home energy, was cut by more than \$700 million. And some of that has been reinstated in the budget committee. And there will be an amendment which I will offer to try to put more in. But if we do not have adequate funding for LIHEAP, it has to come from somewhere. And the education items are on the line.

PRIVATE MANAGEMENT OF PUBLIC SCHOOLS

We had a very useful hearing on January 25, the first day we were in session, on private management, where there was very interesting testimony about economies in private management—a subject which you and I discussed last year. Since that hearing, Massachusetts schools have undertaken more along the private management line. And we were successful in keeping in the conference committee on the Goals 2000 program flexibility for local school boards to use some of that money on some of the exploratory ventures on private management. I will want to ask you about that when the questions and answers begin.

LITERACY TRAINING FOR PRISONERS

I want to touch very briefly on the problem of prisoner education, because there has been an enormous amount of rhetoric on three strikes and you are out. And I have long been an advocate of life sentences for habitual criminals, but having some experience in the prosecution field, know that judges will not impose those sentences however you write the mandatory sentencing law, if on an individualistic basis there is not a feeling that the convict has had a chance. And I believe it is indispensable to do much more on realistic rehabilitation with literacy training in prisons and job train-

ing—something I intend to take up with the Secretary of Labor—and these are subjects that I have had legislation pending on since I came here in 1981.

VIOLENCE AND TEEN PREGNANCY

Right now, there is enough public furor over career criminals that I think we can provide more impetus for this kind of realistic rehabilitation as a prerequisite for the life sentences. It is also humanitarian for the inmate. But I think this is something that we need to address on a priority matter. And I also want to talk to you about school violence and about teen pregnancy as some of the premier priority items which I think we have to address. And, of course, there is a great deal more, but I am going to abbreviate it at this point so that we can move on to our colleagues and listen to your testimony.

Thank you.

Senator HARKIN. Thank you, Senator Specter.

Senator Murray.

OPENING REMARKS OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you, Mr. Chairman.

I do not have an opening statement. I just join with the committee in welcoming the Secretary here today. It seems like education is the solution to every challenge that we face in this Nation, and I share the Chair's concern with the budget cuts and how we are going to proceed. And I look forward to your testimony this morning.

Senator HARKIN. Thank you, Senator Murray.

And our distinguished ranking member of the entire Appropriations Committee, Senator Hatfield.

Senator HATFIELD. Thank you, Mr. Chairman.

I have no opening statement.

Senator HARKIN. Thank you, Senator Hatfield.

Senator Stevens.

OPENING REMARKS OF SENATOR TED STEVENS

Senator STEVENS. Mr. Chairman, I just came by. We have another subcommittee meeting. But, in respect to my good friend, the former Governor, I wanted to stop by and tell him we are all looking forward to try to work with him to work out these difficult problems.

If there is any number on the chairman's charts that bothers me it is the safe and drug-free schools reduction. It is something that we really have to deal with, I think, in some way. I am disturbed about the provision that is in the existing budget resolution that cuts discretionary spending, both from the point of view of how much would be applied to this budget and how much will be applied to defense.

So, that will be a difficult problem for us, I am certain. But I do appreciate the opportunity to greet the Secretary this morning.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Stevens.

Senator Cochran.

OPENING REMARKS OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, let me join you in welcoming the Secretary. We are glad that he is here and presenting the administration's budget to us this morning. I want to commend you for some of the priorities that you identify in the budget request. Specifically the funds for chapter 1, and one-half of those going out under the concentration grant formula, which we applaud.

We are also pleased to see the funds included for the new Office of Technology, and \$50 million for education technology through that office. And there are other parts of the budget that we think you have made good, strong commitments for—programs that are important in not only my State, but throughout the country. The historically black colleges and universities facility improvement loan guaranties, for example, will be very important, and many others.

FEDERAL DIRECT STUDENT LOAN PROGRAM

When the chairman was talking about the fact that we are being squeezed and there is a noose around us, I was thinking that we ought to put a noose around one of the new starts that is provided in this budget request, and that is the \$345 million which the administration is asking for this committee to provide for the new direct lending program for college loans. I remain very skeptical about whether that is smart or not.

We are beginning to hear from college administrators and people who are looking at the fine print, and realizing this is a program that is going to cost more than it saves. This \$345 million, for example, is new money that would not be necessary if we were not starting up a new program. It seems to fly in the face of the reinvention of government idea, where we are to look for competitive forces in the market to help hold down costs of programs. And here the Government is abolishing all the competitiveness in this program, creating a new Federal program, hiring a lot of new employees to get started on something that is really going to be a big, massive problem.

And I hope that this committee will take a hard look at this, Mr. Chairman, as we review our budget request from the Department of Education.

Senator HARKIN. Thank you, Senator Cochran.

SUMMARY STATEMENT OF SECRETARY RICHARD W. RILEY

Mr. Secretary, again, welcome to the subcommittee, and please proceed as you so desire.

Secretary RILEY. Thank you so much, Mr. Chairman and members of the committee. It is a pleasure to have with me our Under Secretary of Education, Dr. Mike Smith, and several others, Sally Christensen, Tom Skelly, and others, who are here. Three assistant secretaries, I am pleased, will constitute a panel which will be available for you upon my completion.

It is a pleasure to have this opportunity to testify in support of President Clinton's fiscal year 1995 budget for the Department of Education. I would like to summarize my testimony for you and request that the full statement be included in the record.

Senator HARKIN. Without objection, it will be included.

Secretary RILEY. We are most enthusiastic about our budget this year, Mr. Chairman. I understand the austerity as you have portrayed it with your graphics and your statement, and others in their comments, but it is a very important area, and I think we all are agreeable to that.

It demonstrates the President's commitment to American education by his statement here in his budget request. It reflects the emergence of the Federal Government as a real partner with communities and States as they pursue the national education goals, which we think are extremely important.

FISCAL YEAR 1995 DEPARTMENT OF EDUCATION BUDGET REQUEST

It seeks to prepare our children and adults for the new century. And, in that line, we are requesting \$26.1 billion in discretionary funds for the Department, an increase of \$1.7 billion, as was pointed out, or 7 percent over our 1994 appropriation. And this is one of the largest increases of any agency in the President's 1995 budget.

THREE POLICY THEMES UNDERLYING REQUEST

Three major policy themes encompass our proposed program budget: One, providing a world-class education for all children; two, affording opportunities for high school youth to prepare for challenging, high-wage jobs; and, three, ensuring access to postsecondary education for all students.

Interwoven into these themes is a major effort to strengthen and improve the Department's capacity to manage its programs effectively and to respond to the demands of communities and States as they seek to reform education.

GOALS 2000—CATALYST FOR CHANGE

I would like to highlight for you a few of our highest priorities. The Goals 2000: Educate America Act is the cornerstone of all of our elementary and secondary education proposals. It is not just another Federal program; it is really a framework for helping teachers and schools and parents bring about the kinds of changes needed to provide a world-class education for every child in America.

Goals 2000 will promote high standards in a more challenging curriculum for all students. And it will support the development of new instructional materials and methods, including better use of technology in the classroom. It will provide flexibility, coupled with responsibility, for student performance. And it will encourage stronger partnerships among parents, schools, and communities.

Most importantly, it is the key to getting all education resources—Federal, State, and local—moving in the same direction to improve the quality of our schools.

I want to express my appreciation once again to the members of this committee for our \$105 million 1994 appropriation, which will enable communities and States to begin this year to plan and implement this significant effort.

REAUTHORIZATION OF ESEA

Our next priority is the Elementary and Secondary Education Act reauthorization. Encouraging school districts and States to set high standards for students as encompassed in Goals 2000 is also at the very heart of the ESEA reauthorization proposal. We want to promote the integration of Federal programs into ongoing locally based reform efforts, rather than merely providing supplemental instruction to narrow categories of students for a small part of the school day. We are requesting \$10.5 billion for the reauthorized ESEA programs, an increase of \$1 billion over the 1994 appropriation.

TITLE I GRANTS TO LOCAL EDUCATIONAL AGENCIES

This amount includes \$7 billion for title I grants to local educational agencies—formerly chapter 1, now title I—for the education of disadvantaged students—an increase of \$664 million, or 10.5 percent over 1994.

We seek to shift funds to the highest poverty schools, require States to set high standards for educating title I students, expand schoolwide programs, and increase parental involvement.

And, Senator, I appreciate your statement regarding the targeting aspect of this approach.

EISENHOWER PROFESSIONAL DEVELOPMENT PROGRAM

No education reform effort can succeed without competent, well-trained teachers. For the proposed Eisenhower Professional Development Program, we are requesting \$800 million, an increase of \$145 million, or 22 percent, over the combined 1994 appropriation for the chapter 2 block grant, and the Eisenhower Mathematics and Science Education Programs.

This initiative would support high-quality, intensive training to enable teachers to teach to high standards in all core academic subjects.

SAFE AND DRUG-FREE SCHOOLS REQUEST

All of our efforts to reform American education will also be to no avail unless we provide children with a safe and disciplined environment conducive to learning. To help rid our schools of the violence plaguing so many of our classrooms, we are requesting \$660 million for safe and drug-free schools, an increase of \$188 million, or 40 percent.

EDUCATIONAL TECHNOLOGY INITIATIVE

We are seeking \$50 million for a new educational technology initiative that was referred to by several of you. It is an initiative that would accelerate the use of advanced information technologies to help all learners reach high standards. This initiative would support local and State efforts to integrate technology into the curriculum, improve the technical assistance available to schools and school districts, and develop new models for professional development.

Our administration is working hard to help build a new information superhighway, and teachers and students alike must be prepared to take advantage of the educational benefits that will flow from this new technology.

OTHER ELEMENTARY AND SECONDARY PRIORITIES

Other high priorities in our elementary and secondary education budget include bilingual education programs for limited English proficient students, expanding opportunities for children with disabilities, and supporting research, statistics, and assessment to develop and provide the latest information on what works in teaching and learning to teachers, administrators, parents, and policy-makers.

SCHOOL-TO-WORK OPPORTUNITIES ACT

The next priority, preparing students for work. One of the President's highest priorities is to address the needs of the vast majority of our high school youth who go directly into the work force. For the proposed School-to-Work Opportunities Act, we are requesting \$150 million, an increase of \$100 million over 1994. The President's budget includes an identical amount for the Department of Labor, which you are familiar with.

These grants will help States and communities develop and implement systems to prepare high school youth for challenging high-wage jobs and future education. We have been working closely on a daily basis with the Department of Labor to get this initiative under way, and I am most proud of this interagency cooperation among staff and certainly Secretary Reich and myself.

Other related priorities are tech-prep education, which combines academic instruction and vocational training during the last 2 years of high school and the first 2 years of postsecondary education; adult education basic State grants; and work place literacy partnerships.

ENSURING ACCESS TO POSTSECONDARY EDUCATION

The next priority, ensuring access to postsecondary education. We are committed to ensuring access to postsecondary education to all students. At the same time, we must also streamline and simplify the delivery of grants and loans to students. We must protect the taxpayers' substantial investment in student financial aid by ensuring administrative efficiency and integrity in these programs.

Our 1995 estimate for grants, loans, and work-study opportunities for postsecondary students is \$11.2 billion. These Federal funds will generate over \$28 billion in aid, including new loan capital—an increase of \$1.2 billion—for 6.7 million students. It is hard to realize how many students depend on those funds. That is a gigantic number. Forty-three percent of all full-time undergraduate students receive help from these Federal student aid dollars.

FEDERAL DIRECT STUDENT LOAN PROGRAM

We will expand the Federal Direct Student Loan Program from 5 percent to 40 percent of overall student loan volume. The Depart-

ment has moved quickly and effectively to implement the new system of direct lending, which will simplify student loan delivery, provide new flexible repayment options, and significantly reduce the cost to taxpayers of Federal student loans.

And, Senator, I am sure we will get into some further discussion on that, and I will welcome that.

PELL GRANT PROGRAM REQUEST AND SHORTFALL

For the Pell Grant Program, our \$6.4 billion request would allow us to raise the maximum grant award by \$100, from \$2,300 to \$2,400, and provide awards to an all-time high of 4.1 million students.

Our request also includes \$118 million to pay off the entire remaining estimated Pell Grant Program funding shortfall which we inherited from prior years.

I know your committee has expressed concern about the shortfall, and I am happy to report that a combination of conservative estimates, slower application growth, and appropriations have greatly reduced the estimated shortfall. We have continued to follow a conservative approach in estimating Pell grant costs for 1995, and we will continue to monitor closely applicant and eligibility data to make sure our estimates are accurate.

FEDERAL WORK-STUDY PROGRAM REQUEST

We would fund the Federal Work-Study Program, which is an outstanding program, at \$717 million, an increase of \$100 million, or 16 percent. This will support 829,000 work-study awards, or 116,000 more than in 1994.

We would also increase from the currently authorized 5 percent to 10 percent the amount of funds that institutions must award to students working on community service jobs.

STATE POSTSECONDARY REVIEW PROGRAM

We are requesting \$35 million for the State Postsecondary Review Program, an increase of \$14 million, or 65 percent. States are crucial partners in our efforts to protect the Federal student investment and the interest of student consumers.

PROPOSED PROGRAM CONSOLIDATIONS AND ELIMINATIONS

While our 1995 budget is responsive to the challenges facing American education, we think it is also responsible. We are proposing a number of program consolidations and eliminations that will both improve services to our clientele and maximize the effective use of scarce Federal dollars.

HOUSE DIRECTED REPORT ON PROGRAM CONSOLIDATIONS

Last year, the House Appropriations Committee directed the Department to examine the feasibility of consolidating programs serving the same populations and directed toward similar outcomes, and to prepare a report for use by Congress in enacting the ESEA reauthorization in the 1995 budget. We recently submitted this report. And I believe that the Vice President's National Performance

Review, the administration's proposal for authorizing the Elementary and Secondary Education Act and our 1995 budget request all show that we have given careful consideration of this issue.

For instance, we are proposing to replace the Eisenhower Science and Mathematics Education Program and chapter 2 State grants with a new coherent teacher development program, and to consolidate the existing 49 technical assistance centers in elementary and secondary education into a single network of 10 to 15 comprehensive regional centers.

We would also eliminate \$649 million in funding for 33 programs, that have accomplished their purpose, that duplicate other activities, or are more appropriately carried out with non-Federal resources. We have redirected all of these dollars to higher-priority activities within the Department's budget.

In summary, Mr. Chairman and members of the committee, I believe that our budget clearly demonstrates the high priority that President Clinton places on education and his commitment to provide the resources needed to bring about real change in our schools.

PREPARED STATEMENT

Education, however, is just one of the investments in human capital that are included in the President's budget. And I urge your committee to continue to give education and discretionary programs in health and training the same high priority that the President has afforded them, in your deliberations and in your section 602(b) allocations.

I thank you, Mr. Chairman, and I will be happy to answer any questions that you may have.

[The statement follows:]

STATEMENT OF RICHARD W. RILEY

Mr. Chairman and Members of the Committee:

It is a pleasure to be here today, and to have this opportunity to testify in support of President Clinton's fiscal year 1995 budget for the Department of Education.

We are most enthusiastic about our budget this year, Mr. Chairman. It demonstrates the President's commitment to American education. It reflects the emergence of the Federal Government as a partner with communities and States as they pursue the National Education Goals. And it seeks to prepare our children and adults for the 21st century.

We are requesting \$26.1 billion in discretionary funds for the Department, an increase of \$1.7 billion, or 7 percent, over our 1994 appropriation. This is one of the largest increases for any agency in the President's 1995 budget. Including funding of \$5.6 billion for entitlement programs, our total budget would rise from \$28.8 billion to \$31.7 billion, an increase of \$2.8 billion or almost 10 percent.

Over this past year, as you know, we have been working with Congress on a comprehensive set of legislative proposals on which our budget is based--the Goals 2000: Educate America Act, the reauthorizations of elementary and secondary education programs and the Office of Educational Research and Improvement, the School-to-Work Opportunities Act, and the Safe Schools Act. Congress is now moving quickly toward approving these measures, and we are eager to implement these new initiatives and reforms of existing programs.

Three major policy themes encompass our proposed program budget: Providing a world-class education for all children; affording opportunities for high school youth to prepare for challenging, high-wage jobs; and ensuring access to postsecondary education for all students. Interwoven into these themes is a major effort to strengthen and improve the Department's capacity to manage its programs effectively and to respond to the demands of communities and States as they seek to reform education. Within the context of these themes, I would like to highlight for you some of our highest budget priorities.

GOALS 2000: EDUCATE AMERICA

Goals 2000 is the cornerstone of all our elementary and secondary education proposals. It is not just another Federal program, but a framework for helping teachers, schools, and parents bring about the kinds of changes needed to provide

a world-class education for every child in America. Goals 2000 will promote high standards and a more challenging curriculum for all students. It will support the development of new instructional materials and methods, including better use of technology in the classroom. It will provide flexibility coupled with responsibility for student performance. It will encourage stronger partnerships among parents, schools, and communities. Most importantly, it is the key to getting all education resources--Federal, State, and local--moving in the same direction to improve the quality of our schools.

Unlike earlier reform proposals, Goals 2000 is the first comprehensive Federal effort that will serve as a catalyst to upgrade the quality of education for all students in all 85,000 public schools in America's 15,000 school districts. Our budget includes \$700 million for Goals 2000 in 1995, and calls for \$1 billion a year beginning in 1996.

Most of this funding will support grants to local school districts and States to develop and implement comprehensive improvement plans that include high standards, improved assessments, strategies for professional development, and other changes designed to encourage all students to learn to those high standards.

I want to express my appreciation once again to the members of this Committee for our \$105 million 1994 appropriation, which will enable communities and States to begin this year to plan and implement this significant effort.

ELEMENTARY AND SECONDARY EDUCATION ACT (ESEA) REAUTHORIZATION

Encouraging school districts and States to set high standards for students, as encompassed in Goals 2000, is also at the heart of our ESEA reauthorization proposal. We want to promote the integration of Federal programs into ongoing, locally based reform efforts rather than merely providing supplemental instruction to narrow categories of students for a small part of the school day.

We are requesting \$10.5 billion for the reauthorized ESEA programs, an increase of \$1 billion over the 1994 appropriation.

This amount includes \$7 billion for Title I Grants to Local Educational Agencies for the education of disadvantaged students, an increase of \$664 million or 10.5 percent over the 1994 level. Under our reauthorization proposal, 50 percent of these funds would be allocated through a revised concentration grant formula designed to shift funds to the highest-poverty schools. The reauthorized program also would require States to set high standards in their plans for educating Title I students, would expand the schoolwide program approach, would emphasize intensive and sustained professional development, and would increase parental involvement.

Our 1995 request also provides \$118 million for the Even Start program, an increase of \$26.6 million or 29 percent. This family literacy program both

prepares young children to enter school and enables their parents to gain the basic literacy skills to reinforce their children's learning.

No education reform effort can succeed without competent, well-trained teachers. For the proposed Eisenhower Professional Development program, we are requesting \$800 million, an increase of \$145 million or 22 percent, over the combined 1994 appropriation for the Chapter 2 Block Grant and the Eisenhower Mathematics and Science Education programs. This initiative would support high-quality, intensive training that will enable teachers to teach to high standards in all core academic subjects, such as English, history, mathematics, science, geography, foreign languages, and the arts.

All our efforts to reform American education will also be to no avail unless we provide children with a safe and disciplined environment conducive to learning. To help rid our schools of the violence plaguing so many of our classrooms, we are requesting \$660 million for Safe and Drug-Free Schools, an increase of \$188 million or 40 percent. A major thrust of our proposal is to expand the existing program so that it can address violence and discipline problems as well as drug abuse.

We must also ensure that limited English proficient students meet the same challenging standards expected of all children. Our request includes \$254 million for Bilingual Education programs, an increase of almost \$27 million or 12 percent over 1994.

We are seeking \$50 million for a new educational technology initiative that would accelerate the use of advanced information technologies to help all learners reach high standards. This initiative would support local and State efforts to integrate technology into the curriculum, improve the technical assistance available to schools and school districts, and develop new models for professional development. Our Administration is working hard to help build the new "information superhighway," and teachers and students alike must be prepared to take advantage of the educational benefits that will flow from this new technology.

OTHER ELEMENTARY AND SECONDARY EDUCATION PRIORITIES

We are committed to expanding opportunities for persons with disabilities and to helping States and localities improve education and training for these individuals. For Special Education programs under the Individuals with Disabilities Education Act, we are requesting \$3.3 billion, an increase of \$186 million or 6 percent. This will help States and communities provide a free appropriate public education to all children with disabilities and ensure that infants, toddlers, and preschoolers with disabilities start school ready to learn.

Collecting and disseminating information on schools and teaching has been a clear Federal mission since the original Department of Education was created in 1867. Today this function is more critical than ever as our Nation seeks to reform its education system. For research, statistics, and assessment programs in the

Office of Educational Research and Improvement, we are requesting \$191 million, an increase of \$35 million or 23 percent. This will help OERI develop and provide the latest information on teaching and learning to teachers, administrators, parents, and policymakers.

PREPARING STUDENTS FOR WORK

One of President Clinton's highest priorities is to address the needs of the vast majority of our high school youth who go directly into the workforce. Unless those who do not enter or finish college have the skills to produce quality goods and services in our technologically oriented society, America will not prosper in the global economy. In fact, the United States is one of the only advanced Nations that does not have a comprehensive, formal system to help students prepare for the workforce.

For the proposed School-to-Work Opportunities Act, we are requesting \$150 million, an increase of \$100 million over 1994. The President's Budget includes an identical amount for the Department of Labor. These grants will help States and communities develop and implement systems for preparing high school youth for challenging, high-wage jobs and future education. We have been working closely, on a daily basis, with the Department of Labor to get this initiative underway, and I am extremely proud of this fine example of interagency cooperation among staff at all levels in both Departments.

States and communities will have great flexibility in developing their systems, but each school-to-work program will include both school-based learning tied to the high academic and skill standards of Goals 2000 as well as work-based learning that offers work experience and mentoring in an occupational area.

We also are requesting \$114 million for Tech-Prep education, an increase of \$10 million or almost 10 percent over 1994. This program supports one of the most promising approaches for improving the transition from school to work by combining academic instruction and vocational training during the last two years of high school and the first two years of postsecondary education.

In addition to activities focused on preparing students for the workplace, the budget includes increases for programs that improve literacy among the adult population. The recently released National Adult Literacy Survey found that up to 90 million adults in this country have serious problems with literacy, and about half that number, or 40 to 44 million, function at the lowest level defined by the survey. We are requesting \$267 million for the Adult Education State Grant program, an increase of \$12.4 million or nearly 5 percent. The budget also provides \$24 million--an increase of \$5 million or 27 percent--for the Workplace Literacy Partnerships program.

ENSURING ACCESS TO POSTSECONDARY EDUCATION

We are committed to ensuring access to postsecondary education for all students. At the same time, we must streamline and simplify the delivery of

grants and loans to students, and we must protect the taxpayers' substantial investment in student financial aid by ensuring administrative efficiency and integrity in these programs.

Our 1995 estimate for grants, loans, and work-study opportunities for postsecondary students is \$11.2 billion. These Federal funds will generate over \$28 billion, including new loan capital, an increase of \$1.2 billion, for aid to some 6.7 million students. Forty-three percent of all full-time undergraduate students receive help from these Federal student aid dollars.

We will expand the Direct Student Loan program from 5 percent to 40 percent of overall student loan volume. The Department has moved quickly and effectively to implement the new system of direct lending, which will simplify student loan delivery, provide new, flexible repayment options, and significantly reduce the cost to taxpayers of Federal student loans.

To make the Direct Loan program a success and to improve the management of our other student aid programs, we will be hiring additional staff to strengthen financial management and monitor postsecondary institutions. President Clinton recognizes the need for additional resources to run these programs well and prevent fraud. To allow us to hire the people we need to get the job done, he has granted to the Department a waiver from his Executive Order to reduce Federal employment.

For the Pell Grant program, our \$6.4 billion request would allow us to raise the maximum grant award by \$100, from \$2,300 to \$2,400, and to provide awards to an all-time high 4.1 million students. Our request also includes \$118 million to pay off the entire remaining estimated funding shortfall in the program that we inherited from prior years.

I know your Committee has expressed concern about the shortfall, and I am happy to report that a combination of conservative estimates, slower applicant growth, and appropriations has greatly reduced the estimated shortfall. We have continued to follow a conservative approach in estimating Pell Grant costs for 1995, and we will continue to monitor closely applicant and eligibility data to make sure our estimates are accurate.

Our budget also increases funding for the Work-Study program by \$100 million, or 16 percent, over 1994. Our total request of \$717 million will support 829 thousand work-study awards, or 116 thousand more than in 1994. We are also proposing to increase, from the currently authorized 5 percent to 10 percent, the amount of Work-Study funds institutions must award to students working in community service jobs.

We are requesting \$35 million for the State Postsecondary Review Program, an increase of \$14 million or 65 percent over 1994. States are crucial partners in our efforts to protect the Federal student aid investment and the interests of student consumers. Our request would expand the number of problem institutions

reviewed by State postsecondary commissions and help protect students and the taxpayers from abuse of Department programs by unscrupulous schools.

PROGRAM CONSOLIDATIONS AND ELIMINATIONS

While our 1995 budget is responsive to the challenges facing American education, it is also responsible. We are proposing a number of program consolidations and eliminations that will both improve services to our clientele and maximize the effective use of scarce Federal dollars.

Last year the House Appropriations Committee directed the Department to examine the feasibility of consolidating programs serving the same populations and directed toward similar outcomes, and to prepare a report for use by Congress in enacting the ESEA reauthorization and the 1995 budget. We recently submitted this report. I believe that the Vice-President's National Performance Review, the Administration's proposal for reauthorizing the Elementary and Secondary Education Act, and our 1995 budget request all show that we have given careful consideration to this issue. For example, we propose to replace the Eisenhower Science and Mathematics Education program and Chapter 2 State Grants with a new program that provides a more coherent national focus on teacher development in the context of education reform. We propose to consolidate the existing proliferation of 49 technical assistance centers in elementary and secondary education into a single network of ten to fifteen regional centers providing comprehensive assistance across program areas. And we are proposing consolidations of activities in other areas such as Safe and Drug-Free Schools, the Chapter 1 Handicapped Program, and programs to encourage minorities to pursue graduate education.

While the Committee directive focused on program consolidation, the Administration believes that maximizing the impact of scarce Federal resources also requires the elimination of programs that are no longer needed. As recommended by the National Performance Review, our budget eliminates \$639 million in funding for 33 programs that have accomplished their purpose, that duplicate other activities, or are more appropriately carried out with non-Federal resources. We have redirected all of these dollars to higher-priority activities within the Department's budget.

CONCLUSION

In summary, I believe our budget clearly demonstrates the high priority that President Clinton places on education, and his commitment to provide the resources needed to bring about real change in our schools. Education, however, is just one of the investments in human capital that are included in the President's budget. I urge your Committee to continue to give education and discretionary programs in health and training the same high priority that the President has afforded them, in your deliberations and in your Section 602(b) allocations.

Thank you, Mr. Chairman. I will be happy to answer any questions you may have.

DEPARTMENT OF EDUCATION

Biographical Sketch

- NAME : Richard W. Riley
- POSITION : U.S. Secretary of Education
- BIRTHPLACE AND DATE : Greenville County, SC; January 2, 1933
- EDUCATION : Furman University, B.A., cum laude, 1954
University of South Carolina, J.D., 1959
- EXPERIENCE
- January 1993-Present : Secretary, U.S. Department of Education
- 1985-1993 : Senior partner, Law firm of Nelson, Mullins, Riley and Scarborough
- 1990 : Institute Fellow, John F. Kennedy School of Government, Harvard University
- 1978-1985 : Governor of South Carolina
- 1967-1977 : South Carolina State Senator
- 1963-1967 : South Carolina State Representative
- 1960-1963 : Attorney, family's law firm with offices in Greenville and Simpsonville, SC
- 1959-1960 : Legal counsel to the Judiciary Committee of the United States Senate
- 1955-1957 : Officer on a mine-sweeper, United States Navy
- PROFESSIONAL MEMBERSHIPS: Member, National Assessment Governing Board Member, Carnegie Foundation Task Force on Meeting the Needs of Young Children Board Member, Duke Endowment
- HONORS AND AWARDS : South Carolina Education Association's Friend of Education Award, three-time recipient Government Responsibility Award, Martin Luther King, Jr. Center, 1983 Connie Award for special conservation achievement, National Wildlife Federation, 1981

INCREASED REQUEST FOR GOALS 2000—EDUCATE AMERICA ACT

Senator HARKIN. Mr. Secretary, thank you for a very comprehensive statement that covered the programs, basically, and the increases that you are requesting.

It is a full plate for us, and I do not mean to belabor the point on the budget, but it is going to be a tough year for us.

I just at the outset again want to compliment you on the direction you are taking in the Department of Education. I think some of these changes are necessary, although I have some problems with some of them, but I am sure they can be worked out.

GOALS 2000: EDUCATE AMERICA ACT

Last year, Mr. Secretary, you only asked for \$420 million for Goals 2000. That is how much is authorized in the bill for 1994. Why now are you asking for \$700 million in 1995 and \$1 billion in the out years?

I have heard some concerns expressed about these huge increases, and just what we are buying with this big increase in money. What are we going to do with all this big increase in Goals 2000? If you might just outline that for us, I would appreciate it.

BASIS FOR INCREASE IN GOALS 2000 REQUEST

Secretary RILEY. All right, Mr. Chairman. Goals 2000 is really the first Federal effort aimed at upgrading the quality of education for all of the 85,000 public schools in this country, 15,000 school districts. It develops, of course, this partnership, really a new role, a real partnership with the Federal Government.

It is, of course, a Federal role that we have debated and discussed, and that you are familiar with, involving setting high academic standards, a goals panel to monitor them, and occupational skills standards. All of those are Federal roles that then are voluntary as far as the States and local schools are concerned, but very, very important information that tells a parent what is a quality education; such as, what should a person in the fifth grade know about math or, in the eighth grade, about science. That is the Federal role and that, of course, is a piece of the funds.

The State role then of implementing comprehensive strategies for real improvement is where the great portion of the money goes. And needless to say, when you get into the 50 States and you get into the 15,000 school districts and 85,000 schools, it is an enormous job for each one of those schools and districts and States to develop action plans that are geared to education reform, to fundamental change, to doing things differently. But an important point is they will do it their way, hopefully with the high State standards, using our standards as a guide. That is a large cost if you are going to impact it properly.

The local role then, of course, is putting all of that into action. And that is extremely important, of course, because the whole concept is bottom-up, and the local role is really where the majority of the money ends up, at the school itself.

GOALS 2000 EXPENDITURES AS CATALYST FOR SCHOOL REFORM

And at that point the key is that Goals 2000 reform funds would really be used to alter the current ways of doing business—things like the use of technology that several of you have a special interest in, or professional development, which is a very important part of all of that, would change and raise standards. It becomes then immediately necessary to raise the professional development standards to teach to those high standards, to bring in technology and all of the other innovative uses for education.

But it is a very big undertaking for this country, and I think all of you agree that it is the most important thing that the country can be about. It will be the first time that we really have somewhat of a handle on developing a national priority for quality education, for excellence in education, for high standards up and down the line in all of our educational efforts.

And it is, needless to say, expensive. But when you take the \$700 million and look at how big the system is and how important this impact will be, I think you will realize that it is a very small Federal investment for quality improvement in a very, very large educational system.

Senator HARKIN. Mr. Secretary, I appreciate that. I assure you that we will be watching how that money is being spent out there. That is a lot of money. As you point out, it is to try to encourage a bottom-up type of systemic reform in education, setting new standards, letting schools develop the ways that they are going to meet those standards within their own environment, within their own school districts. I just do not know why it costs so much money to do that, since they are going to have to do that locally.

NATIONAL DIFFUSION NETWORK AND SCHOOL REFORM

And then we want to get information out, around the country, as to what schools systems are doing to meet those standards. I think one of the agencies that has been most effective in getting information to school districts around the country in terms of innovation, new techniques, procedures, and standards has been the National Diffusion Network. And yet that is sort of being done away with, folded in with something. I do not know what it is doing.

I am concerned as to how, if a local school district is doing something that is innovative, that information gets to the other 85,000 schools around the country so that they can take a look at it and see if it is adaptable to their own school district.

We had a system in place through the National Diffusion Network. I am not certain that, if we are sort of reinventing the wheel here, so to speak, doing away with that and setting up some new structure that is going to cost us a lot of money that I think we are somewhat capable of doing right now is the correct approach.

I do not know if you want to respond to that right now, but perhaps take a look at it later on.

SYSTEMIC REFORM

Secretary RILEY. Well, I might ask Mike Smith, who is Under Secretary and was really one of the leading researchers to develop the concepts of systemic education reform at Stanford, as dean

there. And the whole concept of systemic reform, of course, is to develop within a system in a comprehensive way things that are in sync and are driven by these high standards.

And the whole idea then of having these action plans in every State, in every school district, in every school gives us an opportunity to reach them and to work with them in helping them to develop a plan.

Mike.

Senator HARKIN. I just want to say we are well aware of Mr. Smith's background, his brilliance, and his seminal thinking on education reform, and we welcome him here. Mr. Smith.

DEPARTMENTAL APPROACH TO SYSTEMIC EDUCATIONAL REFORM

Mr. SMITH. Thank you, Mr. Chairman. Two thoughts on this. The first is that there will be \$100 million, we all hope, for Goals 2000 in 1994 with which we will begin to get States and local communities ready to spend this larger increase in 1995. Part of it is really a readiness, it is being aware of what kinds of changes will be required.

The second point, and a related one, goes to your observation about the National Diffusion Network. One of the things that is happening out there now in the States and communities all over the country is that there is local reform. There is a lot of State reform. The chief State school officers are meeting this week. They are spending most of their time talking about systemic State reform and what they are going to do when they receive the Goals 2000 money.

The same kind of thing is happening in local communities. It is happening with superintendents, it is happening with principals. You will hear more testimony about that from Tom Payzant and others, I believe.

That kind of diffusion is happening naturally. It is happening through the professional associations. It is happening through networks of teachers. It is happening through a variety of different kinds of networks.

PROPOSED COMPREHENSIVE, REGIONAL TECHNICAL ASSISTANCE CENTERS

What we have tried to do in thinking about NDN, and thinking about technical assistance in general, is to piggyback on that momentum, to give the kinds of support to all of those professional associations and networks, build on the experience of NDN which has been very powerful in many instances and which is moving over, to some extent, to dealing now with more systemic ideas, but to build on those to put in place something like 10 to 15 really comprehensive centers which can work with State departments, which can work with local agencies to really put out the kinds of information that you are talking about.

It is absolutely critical that that information gets around because we know from lots and lots of research that the most important information that a teacher or a principal needs comes from other teachers and principals.

Senator HARKIN. Will those regional centers replace the regional offices the Department of Education has now, or will they be sort of put together?

Mr. SMITH. They would work very closely with them. They would not replace them. They would be nonprofit private centers. They would not be part of the Government themselves.

Recall that our regional offices—that the Secretary's regional offices are very small. They only have three or four people in them. The other parts of our regional offices deal primarily with civil rights or with postsecondary education, and a little bit with rehabilitation services, and they are really there to monitor and oversee the kinds of grants and activities that go on.

Senator HARKIN. So these regional offices for Goals 2000 will not be the same. They would have a working relationship.

Mr. SMITH. They would not be regional offices per se. They would be technical assistance centers, and they would not just deal with Goals 2000. They would deal with all of ESEA, for example, so they would be able to respond to questions about the relationship between title I and Goals 2000, or to the relationship between drug-free schools and vocational programs.

What they would do would be to combine, as the Secretary said, some 50 or so quite specific technical assistance centers out there that provide information about drug-free schools or provide information about title I evaluation.

Senator HARKIN. The request is for \$70 million for these technical centers for next year?

Mr. SMITH. That is right.

Senator HARKIN. Let me just ask one more question here before I call on other members of the subcommittee.

CHAPTER 1 CONCENTRATION GRANT FORMULA

I appreciate what Senator Cochran said about the chapter 1 funding, and certainly we do have to look at better ways of focusing our money and everything, I understand that. But for the life of me I cannot understand why a poor kid, a disadvantaged child that lives in the State of Iowa is any less needy than a disadvantaged kid who lives in Mississippi or in New York.

In fact, I will make a counterintuitive argument here, that in many cases because of the distribution of poverty in many rural States, that the cost per student for chapter 1 services is higher than it is in a State with a high concentration of poor children; that, in fact, the cost per student would be lower and, in fact, economies of scale I think would dictate that perhaps we ought to take a very careful look on how we focus on concentration formulas, because it will discriminate against those who live in highly rural areas where there may not be heavy pockets of poverty, but where poverty may extend over a broad area.

Second, I do not believe that the concentration approach takes into account the recent past. For example, in my State of Iowa child poverty by Federal Government statistics increased by 21.7 percent in the last decade. This is almost double the national rate.

PROPOSED FORMULA CHANGES TO CONCENTRATION GRANTS

So, the number of our poor children in Iowa has gone double the national rate, and yet under the formula that you are proposing we are going to take a 30-percent cut in chapter 1 funding. A 30-percent cut in chapter 1 funding, I am sure as you heard when you were in my State, Mr. Secretary, will devastate some of these programs.

I mean, you can take a little bit of a cut and you can move things around. A 30-percent cut basically, in many cases, will mean that a chapter 1 office will have to let go teachers and may, in fact, even have to shut down because they cannot operate on what they have left. That means that whole areas of poor kids in Iowa will not have chapter 1 services.

I appreciate the heavy concentrations of poverty in certain States, but I also appreciate the fact that a poor child that lives in Sac City, IA, is no less needy of chapter 1 services than a poor kid that lives in—I am trying to think of a place in Mississippi—Jackson, MS, thank you. And yet that concentration formula really skews it very badly.

So, I would hope that we could work together to find some more equitable formula than what that is, Mr. Secretary.

Secretary RILEY. Mr. Chairman, you are exactly right. When I was in Iowa I did hear that same remark several times, and I understand it. And certainly your suggestion to continue to work—we are most willing and happy to do that.

I would question your referring to the term “discriminate against” because it is really more a situation of triage. The unfortunate fact is we do not have enough resources to really reach all disadvantaged kids and give them the kind of support that chapter 1, title I calls for. And I understand the rural extra burden, that you point out, with the Star Schools, of course.

I think technology, and you are very much into that in a very effective way in Iowa, is going to make a difference, I hope, and we can get more into that I am sure. But some day all schools should have access to the same kind of broad information resources in this country, and that would just be a grand situation.

CONCENTRATING VERSUS SPREADING OUT CHAPTER 1 FUNDS

But I want to explain our position on this a little bit by saying that when you have not enough money to cover everything, by spreading the money out you end up with a lot of schools where there are a large percentage of poor kids that are not served because the school district or the county has to spread the funds as best they can within their region. We just hear of situation after situation where that certainly appears unfair.

But the fact is we have to try to devise formulas to do the most good, and we are absolutely convinced that to put more funds into the targeted areas, those with concentrations of poverty, really is the best way for us to use those funds.

I cannot disagree with you on anything you have said about the unfairness of leaving someone out, but it is simply a fact that we do not have the funds to do everything we would like to do. And

this is, we think, the best way to get the most done with what we have.

IMPACT OF FORMULA PROPOSALS ON IOWA

Senator HARKIN. Well, I appreciate that, but something is going to have to be done because—I mentioned Sac City, IA. That county loses 45 percent and the loss effectively shuts the program down. I do not know how they can operate on that. Woodbury County, Sioux City, 51.6 percent cut. Well, I can go through the rest of them—49 percent, 52 percent cuts, 50 percent cuts, 52 percent cuts. And I am quite familiar with these counties and there are great instances of poverty in those counties.

I might just point out that Iowa, I believe, is 37th in the Nation in median income, I believe, if I am not mistaken, so it is not that we are a real wealthy State. And we have been hit hard by the floods. I do not know that that has been taken into account in the recent demarkation of us as 37th. We are probably lower than that now.

So, again, I appreciate the problems that you have, but I hope you appreciate also that I feel that something more fair has to be worked out. Again I say it just strikes me as unfair that a poor child in an area of Iowa that is eligible for this funding is denied it simply because he or she lives in a small town out in a rural area. That is not right.

We will work it out. Thank you, Mr. Secretary.

Senator SPECTER.

Senator SPECTER. Thank you, Mr. Chairman. On this round, with my colleagues waiting, Senator Hatfield and Senator Cochran, I will ask only two questions and hope to come back to some of the others on a later round, or discuss two topics.

LITERACY TRAINING FOR PRISONERS—MEANS OF REDUCING RECIDIVISM

The first topic that I want to discuss with you, Mr. Secretary, is one which you and I have talked about informally, and also on the record before. And that is the question of literacy training for prisoners.

The issue of crime rises to the top from time to time, and it is there again, and there is a real fervor now on career criminals—three strikes and you are out. It is a subject that I have addressed for a long time since my days as district attorney, and with the armed career criminal bill which we passed in 1984, giving up to life sentences for three time losers found with a gun in Federal jurisdiction.

And I am convinced, and I think there is a lot of empirical evidence to support the conclusion that we will not get judges to impose life sentences unless they feel on an individual basis that the man or woman standing before them has had a chance; that if you release a functional illiterate without a trade or a skill from jail they are back on to a life of crime.

CONSOLIDATING FEDERAL PRISONER EDUCATION PROGRAMS

And we have a variety of programs in your Department—1 percent of basic grants to correctional institutions for vocational education, which is \$9.6 million; 10 percent for adult education, or \$26.7 million; and neglected and delinquent State run institutions; and juveniles and adult correctional facilities, at \$13.6 million.

A \$2 million literacy demonstration program for prisoners which Senator Harkin and I put in last year which you have left out this year—we can handle \$2 million, probably; \$5.1 million for program for prisoners on reducing recidivism. And there are funds in the Department of Labor, and there are also funds on Federal prisons through the Subcommittee on Commerce, State, Justice, and Judiciary.

And rather than get into an extended dialog, I wonder if we might undertake a commitment to try to put these programs together in some coordinated way where we could measure what the effect is on recidivism. And I intend to offer an amendment on the Budget Committee to allocate more funds. We are talking about \$22 billion for fighting crime and in my opinion it is not very well prioritized.

And what I think we need to do, and I would be interested in your response, is to collate the diffuse programs we have today and try to get an evaluation as to what works and what does not work, and use that in a coordinated way so that when people have been subject to realistic rehabilitation, that can be a factor on getting life sentences where they fail.

I would be interested in your response, Mr. Secretary.

INITIATIVES IN CORRECTIONS EDUCATION

Secretary RILEY. Senator, I thank you for your interest in this area, and we have discussed it before. Your suggestion makes real good sense to me. One of the main things we have tried to do is to consolidate, coordinate a number of programs. As you know, we have some 230 programs in the Department, and we ought not to have near that many.

And I have a real interest in correctional institution educational programs. I really do think that is something we absolutely need to get into. The crime bill, as you know, has an ounce of prevention program and other programs that are helpful.

One thing that I would mention to you is our Chapter 1 Neglected and Delinquent Program, which is a significant program. Some 34 percent of the students 20 years of age and younger served by the program are in adult correctional institutions. And that is about \$13.6 million in chapter 1 funds. And that is another program, in line with your suggestion, that we could consider as we look at the package and see exactly what we are doing in this area. I think that makes real good sense.

APPROPRIATIONS OR AUTHORIZING BASIS FOR CONSOLIDATION

Senator SPECTER. Do you know whether we need authorization to do this, or could we in the Appropriations Committee try to put something together which would have some legislative bite to it in

cooperation with you, so that we put it into law to give some greater direction to these objectives which we have just discussed?

Secretary RILEY. Well, I would be happy to work with you all in that regard. I am afraid it would need, probably to get done the kind of thing you are talking about, some sort of authorization to do it. But I think it would be well worthwhile for us to be working in that regard. And, of course, you all can do a great deal if you really put your minds to it, and we will certainly work with you.

Senator SPECTER. Well, there was one precedent for legislation on an appropriations bill. I think Senator Hatfield remembers that it happened several decades ago, but it is not unheard of to have some authorization legislation in an appropriations bill.

Senator Harkin notes that we have an authorization bill coming up. He is making the unusual suggestion of doing it right, I think. [Laughter.]

He says we will do it both ways. Well, fine. We will try the first cut at it, and my staff will be consulting with yours on the authorization, and with your support I think that would help with the authorizers.

TEEN PREGNANCY AND PRENATAL CARE

The second subject that I want to discuss with you briefly—and I have written to you about this and we have talked about it last year on the record, and I would like to put into the record my letter to you dated February 28, and your reply to me dated March 11, so that the record will show a good bit of our activities on the subject of teen pregnancies and prenatal care, et cetera.

[The letters follow:]

LETTER FROM SENATOR ARLEN SPECTER

The Honorable Richard W. Riley
 Secretary
 Department of Education
 Washington, D.C. 20202

January 28, 1994

Dear Mr. Secretary *R. W. Riley*

Last year I wrote to you urging that you join me in developing an initiative to reduce the number of low birth weight births and to improve pregnancy outcomes. The initiative focused on augmenting funding for programs targeted to improving pregnancy outcomes within the jurisdiction of the Labor, HHS and Education Appropriations Subcommittee. After discussing the issue with you during the Subcommittee's hearing on May 12th and during our meeting on September 12th, and after working with Chairman Harkin, an initiative was launched to increase funding for these programs by \$125.5 million.

In your letter of October 26, 1993, you outlined programs proposed in the health care reform legislation and the reauthorization of the Elementary and Secondary Education Act designed to address prenatal care for teen mothers and reduce the rate of unwanted teen pregnancies. I am writing to you today to ask you to join with me in building upon the steps taken last year.

After an additional year of review, I am convinced that real progress toward improving pregnancy outcomes must involve both programs which expand access to, and utilization of, prenatal care, and programs which prevent teen and unwanted pregnancies. The number of babies born to families with only one parent is increasing annually. In 1971, 11.3 percent of births were born to unmarried women. Twenty years later, nearly 30 percent, or 1.2 million babies, were born to unmarried mothers. This was nearly 30 percent of all births. In some cities, nearly two thirds of all live births were born to unmarried women. Many of these mothers are teenagers, have not completed high school, have little vocational training, and lack necessary skills as parents. Until action is taken to reduce the number of children born to unwed mothers, material progress in reducing low birth weight births will remain illusive.

While the solution to this problem is not simple, I believe there are steps that can be taken. First, Congress and the Administration must move swiftly to consider legislation to reform our welfare system and eliminate elements in the system which foster dependence, reward having children, and discourage initiative. Second, as Ranking Member of the Labor, HHS and Education Subcommittee on Appropriations, I believe a pregnancy prevention initiative, targeted to at-risk populations, needs to be launched. This initiative, involving all three Departments within the Subcommittee's jurisdiction, could focus on targeting funding for pregnancy prevention to programs, such as, Comprehensive School Health Education, Head Start, Family Planning, and Adolescent and Family Life, as well as develop materials for initiatives in other education, health, and job training programs which deliver services to at risk populations.

I invite your comments on my proposal and your recommendations on other areas on which we should focus to tackle these difficult problems, which some have labeled as the most critical and basic social problems of our day. I am particularly interested in the funding recommendations in the President's

FY'95 budget for programs within your Department which will educate children and help reduce the incidence of illegitimate births and unwanted pregnancies.

In order to be prepared to discuss this matter with you during the Subcommittee's FY'95 budget hearing expected in March, I would appreciate an expeditious response. Should you have any questions, please do not hesitate to contact me.

Sincerely,



Arlen Specter

LETTER FROM SECRETARY RICHARD W. RILEY

Honorable Arlen Specter
United States Senate
Washington, DC 20510

March 11, 1994

Dear Senator Specter:

I appreciate your letter of January 28, 1994 discussing how we might work together on the important issue of teen pregnancy prevention and reducing the incidence of low birth weight babies. As we both noted when I met with you and Secretary Shalala last September, this is a vexing problem to which there is no easy solution. However, it is also a problem that we must begin to address seriously.

Since my letter to you last October, the Department of Education has taken several steps to work closely with other Departments to develop a strategy in this area. For example, last November, the Under Secretary of Education and the Surgeon General jointly held a meeting with experts on teen pregnancy prevention to hear recommendations on joint approaches. The lessons learned from that and other meetings are being applied in health care reform, welfare reform, and other efforts.

Health education that focuses on reducing risk-taking activity and an increase in access to family planning services and prenatal care are necessary to any strategy. But, for many of our youth, especially those in high-poverty neighborhoods, health education and health services alone are not enough. For youth with low academic aspirations and achievement, little hope of future employment, no caring adult in their lives, and few opportunities for safe, rewarding and productive activities outside of school, access to health education and health services is not a sufficient response to the problem of teen pregnancy. We must do more to ensure that our youth have a chance to be valued and productive members of our society and that youth are told this from an early age.

First, we must look at increasing time horizons and motivation to help young men and women avoid childbearing through activities such as job opportunities and career and college awareness. Second, for those youth in need, we must provide social supports to foster nurturing environments that offer safe and positive ways for youth to fill their days. Mentoring, after-school recreation, academic and cultural programs (such as those that would be supported by the Ounce of Prevention Program), full-day schools, and schools as community centers are all part of building a protective environment for at-risk children and youth. Finally, we must consider how community norms might change -- we need to be supportive of efforts by parents, families, teachers, churches, and other community members to reduce teen pregnancy rates in their communities.

As I noted in my previous letter to you on this subject, currently the Department of Education's major efforts to address

this issue are embodied in our proposals for the reauthorization of the Elementary and Secondary Education Act. Our proposals for counseling, mentoring, and college and career awareness in very high-poverty middle and high schools, for coordination with health and social services, for increased parent involvement through school-parent compacts and other methods, and for promoting extended learning time and keeping schools open longer are all important elements of a comprehensive approach to the prevention of teen pregnancies. As you know, our FY95 budget request for Title I and the Safe and Drug Free Communities program in ESEA (the two programs that support these proposals) is \$8.2 billion, up from \$7.4 billion in FY94. We have also proposed targeting more Title I funds to the Nation's highest poverty counties. Increasing funding for ESEA and targeting funds at those areas most in need will be a significant step in a comprehensive approach to meeting the needs of at-risk youth.

As you know, Goals 2000: Educate America Act has as its first goal "readiness for school" and as its fifth goal "increasing rates of high school completion." Goals 2000 will provide monies to schools, communities and states to design and implement their own strategies to meet the goals and to help our children meet high standards. Each community and school that is serious about readiness and decreasing drop out rates will address, in a unique way, teen pregnancy and related issues. That is why our appropriations request, too, is so important.

We have published two invitational priorities for the Department's Comprehensive School Health Education Program (a copy of which is enclosed). One of the priorities focuses on projects that implement professional development programs for teachers, nutritionists, and appropriate health professionals who provide comprehensive health education to students at risk of having low birth weight babies. Applications are currently being reviewed by a panel of experts. While this program is relatively small, we plan to spend \$4.66 million in 1994, an increase of \$200,000 over the 1993 level, in order to devote more resources to address concerns about youth at risk of having low birth weight babies.

In addition, the President's Health Security Act also contains two initiatives that would go far in supporting one element of a comprehensive teen pregnancy prevention strategy: comprehensive health education and school-based and school-linked health services. While each community will develop a strategy to provide health education and health services that address its major health problems, in many communities health problems of particular concern will include low birth weight babies, drug and alcohol abuse, AIDS/HIV, and unwanted pregnancies. These provisions of the Act were drafted jointly by the Department of Health and Human Services and the Department of Education and reflect our best thinking about how to reduce risk-taking behavior among at-risk youth. Funding these programs will be a key element in support of Administration efforts to reduce rates of teen pregnancies and low birth weight babies.

As you can see, the Department is supporting a variety of initiatives that can be part of a comprehensive approach to teen pregnancy prevention and reducing the incidence of low birth weight babies. And, we are continuing to work, both internally and with other Departments, to develop new and coordinated strategies.

I look forward to discussing this important issue with you further, either at the Subcommittee's budget hearing or in another venue. I would also be pleased for your staff to meet with mine to discuss your ideas for a specific initiative.

Yours sincerely,


Richard W. Riley

Enclosure

[From the Federal Register, Vol. 58, No. 238, Friday, Dec. 10, 1993]

DEPARTMENT OF EDUCATION

Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Management Service, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before January 10, 1994.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer, Department of Education, Office of Management and Budget, 725 Jackson Place NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Cary Green, Department of Education, 400 Maryland Avenue SW., room 4682, Regional Office Building 3, Washington, DC 20202-4651.

FOR FURTHER INFORMATION CONTACT:

Cary Green (202) 401-3200. Individuals who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Management Service, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting

burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Cary Green at the address specified above.

Dated: December 7, 1993.

Cary Green,

Director, Information Resources Management Service.

Office of Special Education and Rehabilitative Services

Type of Review: Reinstatement.

Title: The Performance Report for Early Intervention Program for Infants and Toddlers with Disabilities Program, Under Part H of the Individuals with Disabilities Education Act (IDEA).

Frequency: Annually.

Affected Public: State or local governments.

Reporting Burden:

Responses: 57. **Burden Hours:** 855.

Recordkeeping Burden:

Recordkeepers: 0. **Burden Hours:** 0.

Abstract: States are required to submit an annual report to the Secretary from the State Lead Agency on the status of early intervention programs operating in the State for eligible children. This is to include a description of the services and how funds were spent. The information collected will be used by ED to determine a State's eligibility for receiving a grant award under this program.

Office of Postsecondary Education

Type of Review: New.

Title: Confirmation Report for the Graduate Assistance in Areas of National Need Program Fellowship Recipients.

Frequency: Annually.

Affected Public: Non-profit institutions.

Reporting Burden:

Responses: 150. **Burden Hours:** 150.

Recordkeeping Burden:

Recordkeepers: 0. **Burden Hours:** 0.

Abstract: The confirmation Report for the Graduate Assistance in Areas of National Need Program Fellowship Recipients is needed by university departments to document the students who receive fellowships under the Graduate Assistance in Areas of National Need grant. The U.S. Department of Education needs the form to measure and enforce compliance with the law and regulations.

[FR Doc. 93-30759 Filed 12-09-93; 8:45 am]

BILLING CODE 4000-07-02

(CFDA No. 84.2158)

Fund for Innovation in Education (FIE)—Comprehensive School Health Education Program

AGENCY: Department of Education.

ACTION: Notice of extension of deadline date for transmittal of applications and announcement of additional invitational priority.

SUMMARY: A notice inviting applications for new awards for fiscal year 1994 under the Fund for Innovation in Education (FIE): Comprehensive School Health Education Program appeared on September 24, 1993 in the Federal Register (58 FR 50145). Subsequently, the Congress passed appropriation legislation for the Department of Education. In considering the intent of the Senate's Report accompanying the appropriation legislation, the Secretary has decided to add a second invitational priority to the previously published notice inviting applications for new awards under the FIE: Comprehensive School Health Education Program and to extend the deadline for transmitting applications to allow applicants time to respond to the new invitational priority.

DEADLINE FOR TRANSMITTAL OF

APPLICATIONS: The deadline for applications has been extended from December 10, 1993 to January 21, 1994.

DEADLINE FOR INTERGOVERNMENTAL

REVIEW: The deadline for intergovernmental review has been extended from February 10, 1994 to April 21, 1994.

PRIORITIES: Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in applications that meet one or more of the following invitational priorities. However, an application that meets one or more of these invitational priorities does not receive competitive or absolute preference over other applications:

Invitational Priority 1—School and Family Partnerships

Projects in which schools work in partnerships with families and the community on comprehensive school health education for grades K-12.

Within this invitational priority the Secretary particularly invites applications that address one of the following:

(a) Demonstration or teacher professional development programs that involve new approaches to curriculum, instruction, and assessment in elementary or secondary schools or both.

(b) Projects in elementary or secondary schools or both to provide teachers and administrators with inservice professional development to assist in the implementation of new comprehensive school health education programs.

Invitational Priority 2—Low-Birthweight Babies

Projects which implement professional development programs for pre-service or in-service training of teachers, nutritionists, and appropriate health professionals who provide comprehensive health education to students at risk of having low-birthweight babies. Projects should incorporate the best and most current research on reducing the incidence of low-birthweight babies, including nutrition, prenatal care and effective use of health services, and should serve communities with a high incidence of low-birthweight babies.

FOR APPLICATIONS OR INFORMATION

CONTACT: Shirley Jackson or John Roddy, U.S. Department of Education, 555 New Jersey Avenue, NW., room 300-Q, Washington, DC 20208-5524. Telephone (202) 219-1558. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-3339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Program Authority: 20 U.S.C. 3131, 3153.

Dated: December 7, 1993.

Sharon F. Robinson,

Assistant Secretary for Educational Research and Improvement

[FR Doc. 93-30255 Filed 12-9-93; 8:45 am]

SELLING CODE 0080-01-P

SCHOOLS AS AVENUE FOR DATA ON BENEFITS OF PRENATAL CARE

Senator SPECTER. Mr. Secretary, it seems to me that much more can be done in a very direct way on the problems of teen pregnancies and unwanted pregnancies through the school system. And this is a subject which Senator Moynihan has been the leader on. And to look at Senator Moynihan's charts on the increase of teen pregnancies and unwanted pregnancies is to see a really catastrophic conclusion, which impacts on crime, welfare reform, joblessness, family disunity. I would challenge anyone to identify any

single source of greater problems in America than unwanted pregnancies.

And you and I have talked about this before. And one line would be to have prenatal instruction given to young women in schools, and I realize the Federal Government cannot dictate curricula, but we can suggest, lead, and perhaps put some carrots out there.

A second line is the issue of abstinence, where Senator Denton was the leader in a program on a \$7 million grant, which had been through Health and Human Services, which has been cut out. It is hard to argue against suggesting abstinence. The next line is birth control information, which does become a little touchier.

But let me ask you point blank, why cannot we do something in this appropriations bill which would put some teeth by way of inducements for schools to inform young women about prenatal care when they are pregnant? It is not encouraging them to become pregnant, it is not sex education, it is simply telling them what to do. With a terrible problem on low birthweight babies which are human tragedies and financial tragedies, life-long scars for the children, \$150,000 a piece for medical costs, why cannot we do something forceful to inform young women about prenatal care when they go to school?

Secretary RILEY. Senator, again I appreciate your interest in this subject. I think it is a very, very important one and it leads to problems with violence, drugs, and crime, and everything else on up the line, and it is a prevention matter that should be addressed by this country and by local school districts and schools and communities.

I was in New York visiting a school the other day, P.S. 142 on the Lower East Side. It is in a poor area, but amazing work is being done by people there, and I was very pleased to see it. And it had a class of young women, girls really, the youngest one was, I think, 11 or 12 and the oldest one was 14 or 15. They were all pregnant. But it was a part of an elementary school that was separated. They were not off in the middle school or high school, but it was part of an elementary school separated out from it.

And these young women were getting some of the finest mentoring help, health and other kinds of services right there in class. They are learning and studying how to be productive citizens, as well as good mothers, and how to be responsible in their own health care and future pregnancies and so forth. You know, it was a local effort. It was local people there in that school dealing with that situation. That situation would not work in a lot of schools, but in that school it was working.

So, I think a lot of things are happening, but the availability of services for those girls was very, very helpful, and it deals right with what you are talking about.

INTERAGENCY COORDINATION IN ADDRESSING TEEN PREGNANCY

The complication that we have in the Government oftentimes is the lack of coordination among different agencies, and we are really working on that. Donna Shalala and I have met for long periods of time talking about how we can coordinate better services for pre-school kids, and even about the maternal and infant health issues

dealing with low birthweight babies and other issues. So, I think that is an important part of it.

Our Department will increase the funding for the school health education program in 1994 to \$4.6 million, an increase of some \$206,000 over the 1993 level.

PUBLIC SCHOOLS AS ADVOCATES FOR PRENATAL CARE

Senator SPECTER. Mr. Secretary, what is wrong with an inducement to schools, all schools? I understand schools are different. I believe in boards of education, parent-teachers associations, and local control. But on this issue, what is wrong with inducing all schools to say simply, if you are pregnant consider prenatal care?

Secretary RILEY. Well, I personally see not one thing wrong with that. As far as the Federal Government's involvement, I do not have to tell you. It gets into a very sensitive area of local control of what is taught and what is done in the school.

Again, as far as offering help and advice, instructional help, all of those—and I think we could almost do the same thing you are talking about without requiring certain things to be done.

As far as I am personally concerned, I would welcome it, and if it was a relative of mine, I would welcome it. But we get into an awfully difficult intergovernmental issue when you get into those issues.

We have always felt comfortable, and that is what I was pointing out here, in having glue money to help put those forces together and then let local officials decide what to do. Under the reauthorization of the Elementary and Secondary Act, this is how we have approached it, that is, to have additional funds, but the funds are to be used to put the people or the collaboration of the forces together to get the job done, and then let them decide how exactly they want to do it, and then that produces coordination with Health and Human Services.

Senator SPECTER. Well, I am going to defer my questions now because others are waiting, and I will come back to the subject as to birth control on the second round.

And we are getting closer together, Mr. Secretary. This year we are closer than we were last year. We are going to work on this subcommittee to see if we cannot find something which you would find acceptable in terms of giving as big a carrot as we can. We know we cannot order curricula, but as big a carrot as we can.

Thank you.

Secretary RILEY. Thank you, sir.

Senator HARKIN. Thank you, Senator Specter. Senator Hatfield.

Senator HATFIELD. Thank you, Mr. Chairman. Mr. Secretary, I have a number of items and I will only take the time to cover a couple.

REDUCTION OF LIBRARY PROGRAMS FUNDING

First of all, let me make an observation. I note that you have wiped out the library programs in your 1995 budget, public library construction which as you know is that very small amount relatively speaking that multiplies to such vast quantities of dollars because it is the seed money provided smaller communities to get

a proposal before their people to build a community library and to float the bond issues.

We have had at least a dozen small communities, I think, in my State over the years that have availed themselves to \$50,000 for developing a plan for a community library. That is wiped out. Library literacy programs wiped out. College library technology wiped out. Library education and training wiped out. Research and demonstrations wiped out. Research libraries wiped out.

I think that we all recognize the importance of information. In fact, Senator Harkin and I, in devising a so-called medical research trust fund provided that in the 5 percent of what we hope to raise in this, should it be enacted, \$5 to \$6 billion, that the top 5 percent be taken off and 1 percent of that 5 percent by the National Director of the Institutes of Health be identified for the National Medical Library so that that information is dispersed as rapidly as that research information becomes available.

It disappoints me greatly because I think it runs counter to the administration's effort to enhance the so-called superhighway of information and to recognize the availability of technology to make that a reality.

COMMITTEE DIRECTIVE ON THE MULTISTATE LIBRARY NETWORK

Having made that observation, let me turn to one specific thing related to last year's language that we included in your appropriation. In the Senate report we requested that the Department of Education use \$1 million for a project to enhance the existing multistate library network of academic, public, and special interest libraries. This was to be a competitive program.

We have, of course, an interest because Portland State University has moved ahead and given leadership to the idea of correlating all library facilities, public and private, as well as being the repository for all federally dispensed information in order to make that all accessible.

And I am hopeful that in the letter that I wrote to you on this subject, and recognizing all the demands you have from congressional sources as well as your own priorities, I am very hopeful that this coming year you will look at the point of developing again some of these trial or some of these test cases in which the local people and the local institutions are willing to move ahead and to demonstrate their leadership.

Well, first of all, I would stop and ask your response, if you care to make any, as to your priority on libraries.

Secretary RILEY. All right, Senator, let me speak to the directive first with which we certainly concur. The linkage that was shown in the example is a very good one, and one that is worthy of note.

We have not announced a priority under FIE for the purpose of this priority because it would, in our staff's judgment, duplicate another competition which is being conducted in 1994 under the College Library Technology Program. And this project which you describe really fits into that, we think, very clearly. And we have carried that information forward, and I think that your staff is aware of that, and we are trying to address it under this new program competition.

There has been a tremendous appeal for, as you know, and a draw from FIE funds, and we have some difficulties. The directives far exceeded FIE funds, and so this one we felt would be much more applicable under the College Library Technology Program, and we feel like that is going to work out.

DEVELOPMENT OF A UNIVERSITY-LEVEL LIBRARY INFRASTRUCTURE

Senator HATFIELD. Would any of the \$50 million that you have in your request for 1995 possibly be used for developing such an infrastructure at the university or college level?

Secretary RILEY. Yes; we feel that it would, oh yes. Let me ask Mr. Smith if he would address the elimination of several of the library programs, Senator. And as I said to Senator Harkin earlier, we do have the situation in the Department of these 230 programs, and we are trying our best to consolidate some of those things. And I really want to defend ourselves for not making them less important.

We think libraries are extremely important in terms of education, and I will speak back to the technology and the super information highway, but if you, Mr. Smith, would speak to the hard part of that?

Mr. SMITH. Thank you, Mr. Secretary. Senator, as you know, the Department has recommended that both the public library system—the two larger public library programs both be level funded. It is the smaller programs we proposed eliminating, and in part, I think, the eliminations are because the programs are small, they deal with very specific matters. The larger library programs appropriations can deal with those same matters.

Also, there are other funding sources for some of the programs, for instance the college research libraries and the university research libraries get large amounts of funds from endowments and other sources, and I have been associated with three universities and I realize what the level of funding is for those libraries.

LINKING LIBRARIES REAUTHORIZATION TO EDUCATION REFORM

This does not mean that we do not believe that libraries are absolutely critical. In fact, we are now entering into a phase where we are actually looking at the library programs for reauthorization purposes, and we would like to think about a longer range strategy of trying to link the libraries to the kinds of reform that we are doing.

It is not just to strengthen libraries in general but to try to think about strengthening them so they could reinforce the kinds of systemic reform and high standards and so on that we would like to see happen in the schools.

We can imagine all sorts of exciting relationships through technology, in part, through the libraries having on hand materials that the schools need and the students need in the schools, libraries that are open at times when schools are not open so students can come and study in them more often—there are a whole bunch of different relationships that I think could really create a powerful community effect around supporting public school reform.

So, we would like to work with you on that and think about the relationship of libraries to public schools.

Senator HATFIELD. I would like to some time invite you, or invite you now, with a blank check of your time, to come and see the biomedical information center that we have developed in our State, which is the Cadillac of technology in terms of taking the information base of the Oregon Health Science University and dispersing it throughout all of the State of Oregon through technology to the smallest community clinic or hospital or whatever it is. And this information base is two-way, so that there are resources out there that flow back into the university, but also the university resources are dispersed to the Portals Program of Portland State University that is seeking to bring all of these various library resources together in technology.

EDUCATIONAL FLEXIBILITY DEMONSTRATION AMENDMENT

Mr. Secretary, as you know Goals 2000 passed the Senate and now has moved from the Conference Committee back to the respective chambers. I offered the educational flexibility amendment to that, and it was adopted by the Senate.

In the program this year, I have been doing this for 3 years now, the idea was to set up not only the principle of educational flexibility but also to have a demonstration for six States that the Secretary and the State superintendents and the States coordinated their efforts. Now, that was to be mandatory in the Senate version.

The conference compromised that to make it permissive so that the Secretary has that discretion. My question to you is do you intend to carry out any of the demonstration projects provided in the educational flexibility amendment in 1995?

Secretary RILEY. Senator, I followed the development of that concept very closely. I enthusiastically support it, and the answer is yes.

DEPARTMENTAL LIAISON OFFICE FOR COMMUNITY COLLEGES

Senator HATFIELD. Thank you. One last question, Mr. Secretary. In one way I hate to raise it because it is an old saw, but that has to do with the liaison or the position established by legislation for a role for the community colleges.

Now, Mr. Secretary, this goes back to 1990, before your watch. And I encountered the same—what I sense to be a resistance of the Department to move on this subject. Secretary Lamar Alexander said, well, we will have to wait until the election or we will have to do this, then we have to wait until the next administration takes office, so I was given the postponement under the previous administration.

So, this has been a bipartisan kind of response I have had.

Secretary RILEY. That makes me feel better. [Laughter.]

Senator HATFIELD. Mr. Secretary, in your confirmation hearing I raised this issue through Nancy Kassebaum's gracious willingness to speak on my behalf, and I have had any number of communications, as you well know, and I will not recite them. I have them all here on dates. It is 1½ pages now from a total of two administrations, encounters and discussions.

I want to just reiterate that there are more young Americans today attending community colleges and junior colleges in this country than any other postsecondary programs, including higher education institutions.

And I realize, having been in the education profession myself and having launched a community college program in my State, we did not know where to put it. It was a hybrid, and it has been treated much as a stepchild, an unwanted child in the bureaucracy and the hierarchy and the elitism that constitutes an attitude in our educational programs today, at least in part.

I want to commend you on gathering around you extraordinarily well qualified people. I am only urging you to take final action to establish this position established by law, to add to that distinguished group of people that surround you and give you help in becoming a great Secretary of Education. And I really am at a loss to know what next to do or what next step I should take to get this matter finalized.

APPOINTMENT OF COMMUNITY COLLEGES LIAISON

Secretary RILEY. Senator, all I can ask you to do is be patient for a couple of weeks. We agree with your position. The community college is of great importance to this country and you make the case eloquently. I do not know where we would be without them. They really have developed in response to a natural need, but they are a very, very important part of our whole educational system.

Of course, when we pass our school-to-work initiative, you are going to see the quality of students going into community colleges increase tremendously over a period of years, and the numbers of students going into community colleges are going to be tremendous. And an awful lot of them then will go on to a 4-year college, as they choose.

As you know, Dr. Kappner, who will be on the panel that follows us, is my Assistant Secretary. And she, of course, was a distinguished president of Manhattan Borough Community College for a number of years and a very respected college president, and her appointment shows my interest in community colleges.

The community college liaison position is extremely important, and we are in the process of having it filled. And if you would bear with me for just several more weeks we will have that filled and I will be able to write you a letter and tell you that is done. So, I feel very comfortable about it.

Senator HATFIELD. Well, I am glad to hear you do, Mr. Secretary. It has been a courtship on this matter, and if I find myself with a willing associate I would just like to consummate the act at some point in time. [Laughter.]

Secretary RILEY. It shall be done.

Senator HATFIELD. Thank you.

Senator HARKIN. Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you. I am going to ask one question and submit some others for the record, and I may on a second round if the Secretary is available—I know you were just supposed to be here for 1 hour or so and you had other commitments.

REPORTING REQUIREMENTS IN HEA AMENDMENTS—NPRM

But let me just point to this one issue area that I touched on in my opening comments, the subject of college loans and the new direct lending program. I have received a lot of letters from the college and university presidents and administrators back in my State worrying very seriously about the Department's notice of proposed rulemaking [NPRM] pertaining to the Higher Education Act amendments of 1992. And I must tell you that I am very concerned too about the burden that I am hearing about that these reporting requirements will place on colleges and universities.

In particular, I am troubled by the standards to be used by accrediting agencies to evaluate institutions. I am also concerned about the definition of prebaccalaureate vocational education, and the sizable data collections required under the regulations.

I hope, Mr. Secretary, that you will personally take a look at these proposed regulations and reexamine some of them in light of the comments we are getting from colleges and universities, and address them if you can in the final regulations.

Do you have any comment that you could give us or reassurance that you are going to take a look at this before the final regulations are published?

Secretary RILEY. Senator, I can assure you that I will review these regulations very carefully. I am very familiar with some of the concerns of the higher education community that are out there. And, of course, with the 1992 Higher Education Act reauthorization, some amendments that were passed, we are committed of course to have regulations that are consistent with those new provisions in the Higher Education Act.

And we have sent out our draft regulations to the people in the colleges and universities and others in the higher education community inviting their response. We are still in that comment period now. I assure you, we are listening and reading and carefully considering those responses to the NPRM.

David Longanecker, who is Assistant Secretary of Postsecondary Education, will be here on the panel that follows me. He has been all over the country meeting with dozens and dozens of college presidents and financial officers, and I think he can give you a pretty good idea of both their concerns and our efforts to be responsive.

So, the answer is yes; we are very sensitive to that. The process calls for us to put out regulations and then for the higher education community to respond, and I assure you we are going to be very sensitive to that response.

What the Congress has done, though, in terms of tightening down on institutional and program integrity, is really a separate issue from direct lending. And direct lending, we think, is very much on track. We are working hard to make sure that it is done properly, with this initial 5 percent of overall loan volume in 1994, and then, in this 1995 budget, of course, with the expansion of direct loans to 40 percent.

That direct loan expansion, over a 5-year period, as I recall, is still on track to save the Federal Government some \$4.2 billion.

And the cost that is in this budget is very, very small in relation to the overall cost of the guaranteed student loan programs.

The regulations, though, that you're discussing, reflect congressional action to tighten down on defaults and the financial capacity of the institutions, so that all of us can make sure that students receiving Pell grants or student loans are indeed getting a legitimate education, and that it is not a situation where students were brought in and told one thing, and they get their loan and they give the money to the institution and then they have to repay it without getting any education or training in return.

That is what the Congress was concerned about, and we are tightening down as Congress intended. We understand the institutional differences and the concerns, and we are very sensitive to those, and we will attempt to respond while complying with the law, which we see as our responsibility.

Senator COCHRAN. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran. Senator Bumpers.

Senator BUMPERS. I know I got here before Senator Cochran because he was still talking in Energy and Water when I left.

Senator COCHRAN. I was here for 1 hour before you saw me over there.

Senator BUMPERS. That is cheating. [Laughter.]

Senator HARKIN. We are delighted to have you here, Senator Bumpers. [Laughter.]

STUDENT LOAN DEFAULTS—PRIVATE VOCATIONAL SCHOOLS

Senator BUMPERS. Thank you so much, Mr. Chairman. Mr. Secretary, let me pursue just a moment the line of questioning of Senator Cochran dealing with community colleges, student loans, and so on. The problem really is more in private vocational schools than any place else, is it not?

Secretary RILEY. As far as defaults and so forth, that is right.

Senator BUMPERS. Now, all of the community college presidents came to see me the other day, and I suspect they came to see Senator Cochran and other Senators on the Hill, and they have a really legitimate concern. As I understand, today is the deadline for filing comments. Is that correct?

Secretary RILEY. That is right. Yes, sir.

DATE FOR PROMULGATING FINAL RULES

Senator BUMPERS. And then, what? In 2 weeks—how long are you going to take to promulgate the final rules?

Secretary RILEY. We are on track for when it is supposed to be done. May 1.

Senator BUMPERS. May 1?

Secretary RILEY. Yes, sir.

NEED FOR REGULATIONS TO ADDRESS SPECIAL SITUATIONS

Senator BUMPERS. One community college president told me if he had five defaults—it is in a fairly affluent section of the State—if he had five defaults, that would represent a 25-percent default rate for him. Now, you have to bear in mind that some schools have a very low number of student loans, and so it does not take very

many defaults to put them in default. Are you following me on that?

Secretary RILEY. I follow you, yes, sir.

Senator BUMPERS. So, I hope you will take that into consideration as you go through these. And also if the school is in default—this is the 3-year period proposal—if they are in default for 25 percent or more for 3 years, am I correct on this, they lose all their loan and grant benefits? They would be no longer eligible for Pell grants either. Is that correct?

Secretary RILEY. They would lose eligibility for loans.

Senator BUMPERS. So this program would only affect the loan program?

Secretary RILEY. That is right.

EXEMPTIONS TO LOAN DEFAULT SANCTIONS

Senator BUMPERS. All right. Now the other night Senator Levin came up to me on the floor and asked me if I had any objection to an amendment that he was going to put on a bill that I had in dealing with a school—there is an exception for historically black institutions, is that not correct?

Secretary RILEY. That is correct.

Senator BUMPERS. And he has a school that does not actually qualify under the historical category but it is 60 percent black, but he still would not qualify for this exception. And so he asked me if I minded him putting in an amendment that would exempt that school, and I said of course not. Would you have any objection to that?

Secretary RILEY. Senator, I think the law that we are attempting to comply with is the controlling factor, obviously, and I think that is where most of the problems are that you are discussing. I would be happy to consider anything that is reasonable and within the law.

But I might prefer that Assistant Secretary Longanecker, who has been dealing with this thing in great detail and who will follow us here, give the specifics of that, because I do not want to get out of the realm of the law.

What I have asked my staff people to do is to comply with the law. But there are all kinds of interpretations of what it takes to comply with the law, and we are very sensitive to special needs and special problems. So, I would ask you perhaps to run that by him.

I will tell you that my main interest is that we comply with the law that you all have passed.

REGULATIONS NEED TO ADDRESS EXCEPTIONAL CASES

Senator BUMPERS. Well, Mr. Secretary, as you know we often have a tendency to lock ourselves into a situation without thinking about those exceptions out there that we ourselves would have granted had we thought about it. So, the only reason I raised that was to make you aware that as you go through these regulations there are those cases that you must take into consideration.

Secretary RILEY. If you would share the details of this case with me later on I would certainly take a special look at it, and any oth-

ers, because we want to try to see that all schools are treated in a fair way.

Again, as is pointed out, it is awfully hard to pass regulations when on the one hand you have Harvard and Stanford here, and then you have proprietary schools with a completely different clientele of people. And you and I can see clearly that these schools involve wholly different situations, and it is a real challenge to fashion a consistent regulation.

Even schools that have a very low percentage of defaults must provide certain information. At the least, we have to verify that they have a low percentage of defaults so we have to get certain information.

The biggest complaint of some of the big schools is that we are going to require them to do a lot more data determination and reports, and we are trying to minimize these additional burdens as much as we can. And then there is a trigger point, and when it does trigger then, in some cases, they will have to provide significantly more information, and should at that point in time, where there are problematic signals that are very real.

Senator BUMPERS. Mr. Secretary, it is the diploma mills that we are after. You know who they are and I know who they are. They go out and recruit these kids, they get them a loan, get them a grant, and the kids do not get very much out of it. And these institutions are mostly for-profits. I am not kicking all of them. I am sure some of the for-profits are very, very good. But in any event I want to make sure that we do not throw the baby out with the bath water.

DECLINE IN BLACK MALE COLLEGE ENTRANTS

Second, I would like to say what ought to raise a red flag for all of us, black male college entrants are declining. Now, that is a significant problem. I am not an educator so I do not know how to deal with it, but I am telling you that has to be reversed.

For a long time we had a significant increase in the number of African-American young men entering college, but that has been going down. And that is not only dangerous for them, it is dangerous for the country. We can do better than that and we should.

Now, Mr. Secretary, the other day I saw a story in the Washington Post where you had said, or at least you had signed onto—I do not know where the proposal came from, but I wonder if you will describe it for me.

NEED FOR TEACHING OF FINE ARTS AND PERFORMING ARTS

You said that in the future the academic curricula of the schools in this country were going to have to include the fine arts and the performing arts—drama, band, music, that kind of thing. Am I correct? Did I read that story correctly?

Secretary RILEY. That is correct.

Senator BUMPERS. I want you to know, No. 1, that if it is the way I read it, you have got a real cohort here. I have been screaming about this ever since I have been in the Senate.

You go down to the Cummins Prison in Arkansas and I promise you will not find one single person down there who majored in music or drama or literature or any of those things.

ARTS PROGRAM AT CUMMINS PRISON, ARKANSAS

To give you an illustration, I got a grant—Betty got a grant of \$50,000 from the National Endowment for the Humanities when I was Governor of Arkansas. You know, Bill Clinton is not the only young, handsome Governor they used to have down there. [Laughter.]

And she wanted to start an artists program for first graders. Only in the more affluent schools did they have art programs in the elementary schools, or at least at the first grade level.

She had a little money left over, so she started a program down at Cummins Prison, 2,000 inmates down there. You would be amazed how many of those young men down there had a real artistic talent that if some teacher had picked up on at a very tender age they would not have been there.

INCREASING TEACHER SKILLS—SUMMER INSTITUTES FOR TEACHERS

So, No. 1, these summer institutes that the Carnegie Institute started years ago to improve teaching methods and to give teachers more information, particularly in the performing and fine arts—and I have been trying to expand that through the National Endowment for the Humanities, we give them more money every year to fund these summer institutes. And, incidentally, we passed a bill here about 2 or 3 years ago to establish those summer institutes all over America. Senator Pell and Senator Kennedy and I worked a long time on that.

And one of the things that I said was, students or teachers, for example, I do not care if they are mathematics teachers, they ought to be permitted to go to a summer institute where political science, the Constitution is being taught, and they ought not to be limited just to their discipline.

And one of the things I said was, teachers ought to be able to encourage students to engage in art, music, drama, literature, things that give them a great deal of self-satisfaction and self-esteem. If you want to diminish the prison population, in my opinion, that is the best way.

Now, that is my sermon. You tell me about the program.

GOALS 2000, ESEA REAUTHORIZATION, AND ARTS EDUCATION

Secretary RILEY. Well, my main statement is “amen,” if that is your sermon. Let me say this, Senator. If you look at Goals 2000, that is where we have included the arts. Goals 2000 says that the arts and foreign languages, along with English and math and science and history and geography, that these are core subjects for which standards will be developed as to what young people in various grade levels should know about these core subjects.

If you raise those standards, and that is what Goals 2000 is about for all kids—all kids can learn, from the very young, kindergarten, right on through—if you involve them in things that they can connect up with and get excited about in the arts and foreign

language, then it is amazing, I think, what we can do with education. And you are so right.

But then you have to prepare teachers to teach to these high standards in all of these core subjects, including different things like the arts and like foreign language. You will notice that in our elementary and secondary education reauthorization proposal, there is a significant channeling of funds to professional development for all core subjects, including math and science. We currently have the Eisenhower Professional Development Program that is purely math and science, and that is very much included.

But the very reason you say, if you are going to raise the standards you have got to get teachers prepared to teach to these high standards and to these different, diverse student bodies. You talk about African-American males falling off in college. That is a great source of concern to me. The arts, I will tell you, will make a difference on that as years go by. Things that young men and women can connect to and can find their educational excitement in is a whole lot more real to them.

So, I appreciate your comment and I am very, very interested in seeing to it that Goals 2000 and the Elementary and Secondary Education Act fit together to respond to the very situation that you are describing.

Senator BUMPERS. Mr. Chairman, just one other question. I know he is on a time schedule.

Senator HARKIN. Is that correct, Mr. Secretary? Do you need to get going?

Secretary RILEY. That is all right, sir. I am at your pleasure. I have got to be at the House to testify at 2 o'clock.

Senator BUMPERS. Well, that is the reason we call them the lower house. We will keep you a while longer. [Laughter.]

READING HABITS OF STUDENTS AND LIBRARY USE

On libraries, Mr. Secretary, I am constantly perplexed about the reading habits of the Nation in high schools as well as the public. And we have spent a lot of money, a lot of small communities in my State have magnificent libraries, but they are not utilized. They are simply not utilized anything like to the extent they ought to be. And that has been troubling to me.

I do not know—recently, I made a speech someplace for \$1,000, and you know, we have to give that money away now, and I really enjoy that. It makes me always wish I was rich so I could give it away. So, I call the librarian in my little hometown up in western Arkansas, just a little community of 2,000 people. And I said, I was just thinking about subscribing to the New York Times for your library. She said that would be an utter waste. I said, "It would?" And she said, "Yes; I have only one student in this entire high school of roughly 300, 400, or 500 kids who would ever pick it up."

And she is a librarian, so she can do her very best. A lot of that has to start in the home. But one of the things that these summer institutes ought to be doing, and one of the things I always envisioned was that these teachers would learn skills about how to encourage children to read. It is such a magnificent, interesting thing to do and so educational. But we do not read.

I doubt that there is a developed nation on Earth that reads as little as we do. I just sent her \$500 and said do whatever you want to with it, then. But I can remember—and I have to say, this was when I was a freshman in college—I took a course called public opinion and propaganda.

Incidentally, I never will forget when I started taking French as a freshman, I felt so wonderful when I began to learn French. I just could not believe that I was actually being taught another language. I came from pretty far back in the backwoods, Mr. Secretary, so everything intrigued me.

CIVICS EDUCATION AND TEACHING WITH NEWSPAPERS

But we had to read the St. Louis Post Dispatch and the New York Times and the Arkansas Gazette every day in that course. I do not see any reason in the world why we should not have things like that at the high school level also.

Secretary RILEY. Senator, in the Goals 2000 language, while it is not listed as one of the specific core subjects, civics is referred to and highly recommended as an important part of an education in this country. And, therefore, we are in the process of developing standards for civics. And that would deal certainly with the very thing you are talking about.

A lot of teachers teach from the newspaper, the morning paper, and magazines and so forth. And that is another thing about Goals 2000; curriculum development by teachers and the professional development of teachers, all of that happens at the bottom floor in different ways. It will be different in your town than perhaps in downtown Chicago or whatever, but creative teachers, having the opportunity for development, would then use all kinds of creative ways to deal with these various subjects.

But civics, I think, is important. Learning about this country's Government and the local-State relationships and all of the aspects of current events that you and I, when we were coming along, used to talk about, social studies or whatever, the general topic of civics, I think, is very important. And it is covered in Goals 2000.

IMPACT OF HUMANITIES EDUCATION ON CRIME

Senator BUMPERS. Well, just a couple of observations and then I will be finished. No. 1, I have always believed that the humanities ought to be required at the high school level. I think that we just keep spending money on prisons and we keep hacking away at the branches and never getting around to the roots. And the educational system is absolutely vital. It is the key. It is the key to the crime problem in this country.

As I say, I just think when you teach humanities and you give people an appreciation for who we are and where we came from—knowledge is the most powerful thing in the world—it gives people more self-esteem than anything I can think of. And we are doing a lousy job of it. And that is one of the reasons we are becoming increasingly uncivilized in this country.

But you will never get crime under control by putting 100,000 policemen on the streets. That is fine if President Clinton wants to do that. I voted for it. If you put 100,000 police on the street you

might stop a few crimes and you can put a few more people in prison. And that is fine. When people show conclusively that they cannot live in the civilized society, they need to be locked up.

But I can tell you, we are not ever going to achieve greatness in this country putting more cops on the street and spending more money on all of the things we are spending money on and building more prisons. This is fundamental, and you know that. You know my friendship for you and my personal respect for you. And I am delighted that you are Secretary of Education, because I think you understand this much better even than I do.

PRIORITIZING USE OF GOALS 2000 FUNDS

Let me ask you one final question. If we put \$700 million in Goals 2000—when I was Governor, we used to use a rule of thumb, if there is \$1 billion, we have 1 percent of the population, so we figured we were entitled to \$10 million of it. We have about 2.5 million people, Mr. Secretary, and we are going to get, if that rule of thumb holds up, \$7 million.

Now, how would you recommend we spend that \$7 million?

Secretary RILEY. Well, first of all, the points that you made about the importance of crime prevention and education and training and health care—it all fits into that. The very complication that the chairman showed us here of these areas of human investment are the answer to violence and all of the problems with crime or whatever, along with the economy and general quality of life. And so, I hope this committee will be sensitive to the fact that you have those important areas right here, and it is where this country's future lies.

Senator BUMPERS. Mr. Secretary, let me tell you one thing. The President, as you know, is a very good friend of mine. But I could not disagree with him more on some of his language. I hate that term investment. I never know what we are talking about.

When I think of investments, I think about business. And I know we invest in people, but when they say these investments, I never know quite what that means. Any investment in a child is an investment. It always has been and always will be. But when you say investments, I do not know whether that means student loans or vocational education or the school lunch program or what.

Secretary RILEY. I think the term I always use is human investment. And it is how you spend your money. The point is, if you spend it on all of those things, that is part of human investment, as I see it. And I think that is where we are, and that is what is important. And that is really what you all have before you here today.

Did you ask me something else specifically?

Senator BUMPERS. I wanted you to tell me how—we have roughly a \$1 billion educational budget in Arkansas, and you are going to give us \$7 million to reach these Goals 2000, so I want you to tell me what you want us to put the money in.

LOCAL SCHOOL SYSTEMS ULTIMATELY DETERMINE GOALS 2000 PRIORITIES

Secretary RILEY. Well, we have 85,000 schools in this country, and we have 15,000 school districts. And what our plan, of course, would involve is, in a very carefully thought out way, if we are successful in getting the \$700 million—we could use five times that obviously—10 times that—the funds end up going primarily down to the school. And I talked earlier to the Federal role in development of standards and all of those things, and the State role in development of State standards and systemic reform. But the majority of the funds go down to the school district and down to the school.

So, the majority of the funds would be used right there, and in systemic reform, it would be up to the people at the school and the school district to decide what it is in the comprehensive reform plan that they need to spend the money on. In other words, they have got high standards. They are trying to reach those standards. Is it curriculum? Is it teacher professional development? Is it textbooks? Is it parent involvement?

They analyze that, and spend those funds for what they think is best, reaching for these high standards. And they are accountable for better performance of young people. And for assessments that tell who is doing well and who is not. That is the concept, and that is where the money would go.

I do not want to be misleading to say that \$700 million sounds like a lot of money to you and me. You and I at the Federal level know how difficult it is to make a strong impact with \$700 million in something as big as the public schools in 1 year. But over a couple of years, certainly, we think that kind of stimulus would be there in every single school in this country. But it would take several years of that kind of funding to have all of that taking place—to really make an impact.

TITLE I GRANTS TO LOCAL EDUCATIONAL AGENCIES

Senator BUMPERS. How much money are we putting in title I for 1995?

Secretary RILEY. Title I is about \$7 billion.

Senator BUMPERS. About \$7 billion?

Secretary RILEY. Yes.

ASSIGNED HOMEWORK REQUIRING LIBRARY USE

Senator HARKIN. I just wanted to say, Senator Bumpers, with regard to your libraries, you might get hold of your local school board and have them promulgate a policy that would require teachers in grade school and high school to assign homework that requires their students to utilize the public library, and to show that they have on the homework that they turn in.

That is done out in Fairfax County, where my kids attend public schools. I think it has been very successful. In fact, we have got a couple of libraries in our neighborhood that, as Yogi Berra once said, nobody goes there any more because they are so crowded. And they are utilized because the teachers are sending them there to their homework.

Secretary RILEY. Full of rooms, I think, was another statement. Senator HARKIN. That is right.

But they could do that. And I do not think a lot of teachers and school boards do that—require that they do homework that involves the library and using the library. That is just a suggestion. I have seen it done in other places.

PACIFIC BASIN REHABILITATION RESEARCH AND TRAINING CENTER

I am sorry that Senator Inouye could not be here today. He is ill. But he wanted me to ask you, Mr. Secretary, about the Pacific Basin Rehabilitation Research and Training Center. It has a very long history. It is specifically authorized in law. It is in their budget. But we understand that 18 Hawaii staff may have to be laid off due to some budgeting problem.

I am sorry I do not know this specifically myself, but Senator Inouye wanted me to ask that. And I would like, if you do not know the answer, if you could respond for the record. I would sure appreciate that.

Secretary RILEY. We will do that, Mr. Chairman, as a part of the questions answered for the record. And we will respond directly to the Senator.

Senator HARKIN. Thank you.

If you want to take another round, we will take another round. But I am going to limit it strictly to 3 minutes, if that is OK, so we can get the Secretary out.

Senator Cochran, did you have any further questions?

Senator COCHRAN. Mr. Chairman, thank you. That is the last time I am ever going to be nice to Senator Bumpers. [Laughter.]

Senator HARKIN. Keep him over in Energy and Water. [Laughter.]

COORDINATION OF DEPARTMENT AND CPB ON READY-TO-LEARN

Senator COCHRAN. Well, the point is we do have a lot of questions. And, as I indicated, I was going to submit most of these for the record. I did want to ask one thing, though, and that is in connection with funds for the Ready-to-Learn Program. We have an authorization and an appropriation now and there is a budget request for \$10 million for the Ready-to-Learn Program. We appropriated \$7 million last year, and there was a reluctance by the Department to get involved. And this is the development program for high quality preschool television programming, trying to target children who are at home or in day care centers who need special assistance to enter school ready to learn.

I am glad to see that you have requested funds for that. What have you decided, if anything, about how the Department will work with the Corporation for Public Broadcasting [CPB] in this program? Do you have any specific plans?

Mr. SMITH. We are still in the process of talking with them. They had the \$7 million last year, and hopefully this year we will have the \$10 million. And, obviously, we want to integrate the efforts.

TITLE I CONCENTRATION GRANTS BENEFITTING POOR

Senator COCHRAN. One observation, and that is about the comments the chairman was making about the chapter 1 program—now it is title I. I can remember back when it was title I to start with. Did you bring back that?

Secretary RILEY. It is like ties. If you hold them long enough, they will come back. [Laughter.]

Senator COCHRAN. Well, I did compliment you on your priorities in connection with not only the increase in funding for that, but also the targeting of it to the areas of highest concentration of disadvantaged students. I do not know why this is, but I know you are probably aware of the statistics and the research that has been done in this area, but where there are high concentrations of poor students, they tend not to do nearly as well as poor students where there are fewer poor students in the school.

In other words, in Iowa, for example, there is probably a greater likelihood that a poor student will graduate from high school than it is if that poor student is in Mississippi. I do not know why that is, but it is just a fact.

Secretary RILEY. Senator, it is a research-proven fact that a poor child—and I have said this in response to issues about concentration—a poor child has a more difficult time achieving than a child who is not poor. And you can see that often the parents are uneducated or unable to help their child, or whatever the reason. But then, if you put a poor child in a poor school, surrounded by other poor children who are disadvantaged, the statistics are very clear that that child has a double difficulty in achieving. And that is part of the philosophy of our effort to retarget funds.

Senator COCHRAN. Thank you.

Senator HARKIN. Thank you, Senator Cochran.

Senator SPECTER.

Senator SPECTER. Thank you, Mr. Chairman.

SECRETARY'S COMMENTS REQUESTED ON VIOLENCE ISSUES

I know you have to leave in just a few minutes, Mr. Secretary, so I will outline some topics that I would like to have you respond to. I wrote you about violence in schools in a letter dated February 23. And you wrote back, without responding to the specific questions, saying that you look forward to discussing the matter at our hearings. And since there is insufficient time, I would appreciate if you would take a look at the next to the last paragraph of the letter which poses quite a number of questions. And if you would respond to those, I would appreciate it.

Secretary RILEY. Thank you, sir. And we will sure do that.

Senator SPECTER. And we are going to have some other questions for the record, as well.

PRIVATE MANAGEMENT IN PUBLIC EDUCATION

On the subject of private management, after the President in his State of the Union speech on January 25, endorsed the concept of private management—and he doubtless did that after he monitored the hearing of this subcommittee earlier that day, brought to light by the chairman at least—and I would appreciate it if you would

give us in writing your thinking on the concept of private management, and also, to the extent you can, to monitor the programs. We are going to take a look at that in our appropriations bill to see if we can structure some way to monitor those programs.

We have faced some difficult votes on school vouchers and tax/tuition credits which have not passed—which I have not supported because I think that that cut in funding to the public schools would be very problematic in an era of financial distress. But the issue of private management looks to me to have a tremendous potential.

I was impressed to see Ben Schmidt leave the presidency of Yale University to take up this issue. I am impressed with his programs for a school day, which would go from 7 a.m. to 7 p.m., only part of that for educational instruction, with other activities, such as what Secretary Shalala has commented about pregnancy, occurring at 3 to 7 in the afternoon. And I think that we need to explore all the opportunities. And we did succeed over at a tough conference, which I was invited to attend, last week on that subject. And I would very much appreciate your insights.

The superintendent of schools from the District of Columbia appeared at our appropriations subcommittee hearing and announced his intention to pursue privatizing some aspects of the DC School System. And he has since receded from that. And I think there needs to be an evaluation and, if appropriate, encouragement, on that line.

Secretary RILEY. Senator, we will share our view on that. I would say very briefly that your concept of monitoring and evaluating and making sure we are looking at apples and apples and all of the different other necessary research characteristics—that is the right way, in our judgment, to go about it.

I think we need to start off by saying that no concept is a panacea. That education is not all of a sudden going from dark to light with some concept. It is a lot of hard work and people, as you well know.

But anything that is designed to improve the public schools, we are willing to take a look at. And then, if it is shown from monitoring and research that it does, in fact, put more resources in the classroom, and it does, in fact, improve teaching and learning, it is something we are very interested in.

USE OF FILM SCHINDLER'S LIST AS EDUCATIONAL TOOL

Senator SPECTER. A final comment, Mr. Secretary. The red light just went on. Schindler's List has been touted as a great educational tool. And I had intended to ask you about this or call it to your attention in advance of Schindler's List being cited as the outstanding motion picture of the year. And a number of us in the Senate have endorsed some educational programs that are going on around the country—a number of governors have been involved in it—and to the extent that you could give a word of support to Schindler's List as an educational tool, I think it would be enormously helpful, coming from the U.S. Secretary of Education.

And if you would care to give a comment on that, I would appreciate it.

Secretary RILEY. Well, and we will take a look at that. I have seen Schindler's List and it was a very moving experience for me. And I wish every American could see it.

So, let me take a look at what you suggest and see what, within the responsibilities of our office, we could do.

Senator SPECTER. Well, I would appreciate that. I know you do not want to get involved in commercial undertakings, but I think this is a different sort of an endorsement.

Thank you very much, Mr. Secretary.

Secretary RILEY. Thank you, sir.

Senator SPECTER. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Thank you, Mr. Secretary, for being so generous with your time.

Thank you very much, Mr. Smith, also for being here. I look forward to working with you in getting this budget put together.

Mr. SMITH. Thank you, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you, Mr. Secretary. There will be some additional questions which we will submit for your response.

We will take just a short 5-minute recess. We will have our next panel with Thomas Payzant, Augusta Kappner, and David Longanecker. If they could come up to the table. We will just take a short recess.

[A brief recess was taken.]

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE
DEPARTMENT OF EDUCATION DISCRETIONARY BUDGET
AUTHORITY—FISCAL YEARS 1989-94

Question. Insert in the record a table showing discretionary budget authority and outlays for each budget account for fiscal years 1989 to 1994. Include a column showing dollar and percent increases for this period.

Answer. The requested table follows:

HISTORY OF DISCRETIONARY APPROPRIATIONS
Department of Education
(dollars in millions)

Account	1989	1990	1991	1992	1993	1994	Change '89-'94 Amount Percent
Education Reform							
BA.....	0	0	0	0	0	\$155	---
O.....	0	0	0	0	0	19	---
Education for the Disadvantaged							
BA.....	\$4,431	\$5,222	\$6,076	\$6,706	\$6,696	6,912	2,481 56.0%
O.....	4,185	4,482	5,219	6,159	6,615	6,900	2,715 64.9%
Impact Aid							
BA.....	733	732	781	834	840	798	65 8.9%
O.....	755	816	754	795	432	983	228 30.1%
School Improvement Programs							
BA.....	1,163	1,346	1,496	1,587	1,578	1,421	258 22.2%
O.....	969	1,179	1,366	1,502	2,017	1,645	676 69.8%
Chicago Litigation Settlement							
BA.....	0	0	0	0	0	0	---
O.....	6	10	10	13	15	18	12 183.6%
Indian Education							
BA.....	72	74	75	77	78	80	8 11.4%
O.....	66	69	66	69	100	82	16 24.8%
Educational Excellence							
BA.....	0	0	0	90	(90)	0	0 ---
O.....	0	0	0	0	0	0	0 ---
Bilingual Education							
BA.....	197	189	198	225	213	227	30 15.2%
O.....	165	189	187	198	125	257	92 56.0%

HISTORY OF DISCRETIONARY APPROPRIATIONS

Department of Education
(dollars in millions)

Account	1989	1990	1991	1992	1993	1994	Change Amount	'89-'94 Percent
Special Education								
BA.....	\$2,109	\$2,202	\$2,616	\$2,855	\$2,966	\$3,109	\$999	47.4%
O.....	1,881	1,617	2,174	2,243	2,564	3,604	1,723	91.6%
American Printing House for the Blind								
BA.....	5	6	6	6	6	6	1	20.9%
O.....	7	6	8	5	8	6	(1)	-9.7%
National Technical Institute for Deaf								
BA.....	33	36	37	39	41	42	9	25.5%
O.....	36	31	37	31	54	42	6	15.8%
Gallaudet University								
BA.....	66	68	72	77	78	78	12	18.8%
O.....	82	62	71	72	89	78	(4)	-4.8%
Vocational and Adult Education								
BA.....	1,073	1,123	1,246	1,435	1,474	1,481	408	38.0%
O.....	836	1,299	1,084	1,073	1,185	1,311	475	56.7%
Student Financial Assistance								
BA.....	5,814	6,085	6,715	6,928	7,920	8,023	2,209	38.0%
O.....	5,860	5,920	6,334	7,071	7,678	7,421	1,561	26.6%
Federal Family Education Loan Program								
BA.....	0	0	0	44	60	72	72	---
O.....	0	0	0	44	60	48	48	---
Higher Education								
BA.....	566	625	772	828	833	894	328	58.0%
O.....	607	659	615	718	1,042	881	274	45.2%

HISTORY OF DISCRETIONARY APPROPRIATIONS
Department of Education
(dollars in millions)

Account	1989	1990	1991	1992	1993	1994	Change '89-'94	
							Amount	Percent
Howard University								
BA.....	\$179	\$182	\$195	\$212	\$194	\$193	\$14	7.7%
O.....	177	168	163	191	264	208	31	17.8%
College Housing/Acad. Facilities Loan								
BA.....	0	0	0	8	4	1	1	---
O.....	0	0	0	1	1	1	1	---
Ed. Research, Statistics, Improvement								
BA.....	133	166	220	258	266	278	145	109.6%
O.....	90	89	104	155	232	316	226	249.9%
Libraries								
BA.....	137	137	143	147	146	146	9	6.6%
O.....	140	137	143	215	181	166	26	18.2%
Program Administration								
BA.....	250	273	319	292	305	352	102	40.5%
O.....	239	263	296	290	271	365	126	52.8%
Office for Civil Rights								
BA.....	42	45	48	54	56	57	15	35.9%
O.....	44	44	45	52	52	74	30	69.8%
Office of the Inspector General								
BA.....	19	23	25	26	29	29	10	54.9%
O.....	19	21	24	26	30	30	11	59.4%
Total								
BA.....	17,023	18,532	21,041	22,728	23,694	24,354	7,331	43.1%
O.....	16,164	17,063	18,699	20,923	23,015	24,455	8,291	51.3%

DELAYED OBLIGATIONS IN THE DEPARTMENT OF EDUCATION BUDGET

Question. What is the total amount of delayed obligations requested in the 1995 budget and how does this compare to 1994?

Answer. For fiscal year 1995, a total of \$292,125,000 is requested in delayed obligations for the State Grants for Infants and Families program in the Special Education account. Because of the inability of States to establish eligibility for funding for this program in a timely way, the Department has had to carry over most of each year's appropriation into subsequent years for obligation to the States. Therefore, for fiscal year 1995, the Department is proposing to delay the availability of a portion of the funds requested for 1995 in order to conform the availability of funding to the program's obligation patterns. Appropriation language has been proposed that would provide that \$33,000,000 of the total amount requested for Grants to Infants and Families become available for obligation on July 1, 1995, the normal date of availability, and that the remaining \$292,125,000 become available for obligation on September 30, 1995. All funds would remain available for obligation through September 30, 1996.

The Department of Education had no delayed obligations in fiscal year 1994.

NEW PROGRAMS PROPOSED IN THE FY 1995 BUDGET REQUEST

Question. Provide a list of new programs funded in the fiscal year 1995 budget. In the event that the Committee is not able to fund all new programs in the budget, please detail your priorities.

Answer. The programs in the fiscal year 1995 Department of Education budget that are completely new amount to only \$103 million. The list of these proposed programs, and the requested funding level, follows:

Education Reform:

Educational Technology -- \$50,000,000

Education for the Disadvantaged:

Demonstrations of Innovative Practices -- \$20,000,000

School Improvement Programs:

Charter Schools -- \$15,000,000

School Finance Equalization Assistance -- \$8,000,000

Education Research, Statistics, and Improvement:

Ready to Learn Television -- \$10,000,000

The Department believes these new programs to be among those that would make a critical difference in achieving education reform. It is not possible to state that one of these programs is more important than another, since each would make a special contribution toward successfully achieving our goal--to improve America's schools.

CLEARINGHOUSE FUNDING—FISCAL YEARS 1993-1995

Question. Insert a table showing 1993, 1994, and 1995 funding for all clearinghouse activities.

Answer: The information follows, with amounts in thousands of dollars:

<u>Clearinghouse</u>	<u>FY 1993</u>	<u>FY 1994</u>	<u>FY 1995</u>
ERIC Clearinghouses	\$7,046	\$7,046	\$9,000
National Clearinghouse for Mathematics and Science Education Materials	3,472	5,472	5,296
National Clearinghouse for Bilingual Education	958	980	1,000
National Clearinghouse on Literacy Education	300	300	300
National Center for Research in Vocational Education	5,893	6,000	6,000
National Clearinghouse for Alcohol and Drug Information ¹	500	500	(2)
National Clearinghouse on the Education of Children with Disabilities	1,030	1,030	1,030
National Clearinghouse on Postsecondary Education for Individuals with Disabilities	515	528	528
National Clearinghouse on Careers and Employment in Special Education	604	604	604
National Clearinghouse for Children and Youth with Deaf Blindness	<u>325</u>	<u>270</u>	<u>270</u>
TOTAL	20,643	22,730	24,028 ³

¹ Funds for this clearinghouse are transferred to HHS.

² Amount to be determined.

³ Excludes amount to be determined for Alcohol and Drug Information.

PERCENT OF ELIGIBLE STUDENTS SERVED BY CHAPTER 1

Question. Insert a 5-year table showing the percent of eligible Chapter 1 students served.

Answer. Chapter 1 is designed to serve children who are educationally disadvantaged and reside in low-income areas. School districts ultimately determine, based on a local assessment of needs, which children are eligible for services. Because the selection criteria vary from district to district, the number of eligible children also varies.

We have no precise data on the number of children eligible for Chapter 1 services. The following rough estimates are projected from extrapolations of data on the number of public-school students scoring below the 35th percentile on standardized tests:

<u>Year</u>	<u>Chapter 1 Students Receiving Services</u>	<u>Chapter 1-Eligible Students</u>	
		<u>Number Scoring Below 35th Percentile</u>	<u>Percent Served</u>
1990	5,547,570	10,819,000	51%
1991	5,903,619	11,025,000	54%
1992	6,200,000 ¹	11,201,000	55%
1993	6,200,000 ¹	11,407,000	55%
1994	6,400,000 ¹	11,617,000	55%

¹ Estimate.

Note: If the 25th percentile is used instead of the 35th percentile, Chapter 1 would be estimated to serve a higher percentage of students--an estimated 72 percent in 1990, 75 percent in 1991, and 77 percent in 1992-1994.

Even though a substantial percentage of low-achieving children do not receive Chapter 1 services, the most important issue is: Are Chapter 1 funds and services reaching the children who are most in need? Studies document that Chapter 1 funds are not well targeted on the neediest schools and children. Funds are spread thinly across almost all counties and, as a result, almost half of the lowest-poverty schools (those with less than 10 percent poor children) receive Chapter 1 services, while 13 percent of the highest-poverty elementary schools (with at least 75 percent poor children) go without. Also, the poorest schools that receive funding can serve, on the average, only about two-thirds of their eligible children.

**FEDERAL MATH AND SCIENCE EDUCATION FUNDING—
FISCAL YEARS 1989-1995**

Question. Insert a table for fiscal years 1989 to 1995 showing spending for math and science education throughout the Federal Government.

Answer. The information follows, with dollars in millions:

**Federal Government Spending Levels for
Mathematics and Science Education
(CET Category 1 Programs—\$ in millions)¹**

<u>Agency</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>
DOC	NA	\$7.3	\$7.3	\$4.6	\$7.3	\$8.8	\$10.3
DOD	\$340.3	416.0	416.0	423.0	380.9	375.1	389.1
DOE	NA	42.0	64.1	108.8	114.0	139.0	149.0
ED	150.5	152.5	234.8	329.8	391.1	399.4	192.9
DOI	28.5 ²	27.1	40.6	82.5	86.0	85.6	87.3
HHS	329.0 ³	435.4	486.3	442.6	463.9	482.5	518.0
EPA	NA	26.9	6.6	8.3	8.3	9.0	12.3
NASA	37.7 ²	50.9	68.2	77.5	90.9	97.5	101.7
NSF	215.1	277.8	371.7	504.4	539.4	625.1	650.2
SI	NA	NA	NA	10.1	10.1	10.1	10.7
USDA	<u>7.7</u>	<u>19.6</u>	<u>20.0</u>	<u>23.6</u>	<u>22.7</u>	<u>22.6</u>	<u>21.1</u>
Total	1,108.8	1,455.5	1,715.6	2,015.2	2,114.6	2,254.7	2,142.6

¹ Category 1 programs are programs that are specifically mandated or managed as mathematics and science education programs. For the first time in FY 1995, the Committee on Education and Training (CET) also began looking at general educational technology activities.

² Best estimates.

³ HHS was able to provide figures for 1989 only for major programs that currently represent approximately 82 percent of its total spending for mathematics and science education. The remaining programs are scattered throughout many different divisions and would require an extensive inventory.

FEDERAL SHARE OF COSTS FOR SPECIAL EDUCATION

Question. Insert a 10-year table showing Federal support for disability education programs in millions of dollars, as a percentage of cost, and as a percentage of excess cost.

Answer. The following table shows the amount of funds appropriated for the Special Education Grants to States program and the Federal share of the total and excess costs of educating children with disabilities that is provided by this program. For fiscal years 1994 and 1995, the Federal percentage shares of total costs and excess costs are estimates.

Special Education Grants to States—Federal Share of Total and Excess Costs

<u>Fiscal</u> <u>Year</u>	<u>Appropriation</u> <u>(in millions)</u>	<u>Federal Share of</u>	
		<u>Total</u> <u>Costs</u>	<u>Excess</u> <u>Costs</u>
1986	\$1,163.3	4%	7%
1987	1,338.0	4%	8%
1988	1,431.7	4%	7%
1989	1,475.4	4%	7%
1990	1,542.6	4%	7%
1991	1,854.2	4%	7%
1992	1,976.1	4%	7%
1993	2,052.7	4%	7%
1994	2,149.7	4%	7%
1995	2,353.0	4%	7%

TEN-YEAR HISTORY TABLES OF REVENUES AND EXPENSES-- HOWARD UNIVERSITY, GALLAUDET UNIVERSITY, AND THE NATIONAL INSTITUTE FOR THE DEAF

Question. Provide a ten year table showing total expenses and revenue for Howard University, Gallaudet University and the National Institute for the Deaf. For each, break out revenue by (1) total student tuition and fees, (2) private gifts, (3) investment income, (4) Federal funding, and (5) Federal funding as a percentage of total income.

Answer. The information requested is provided in the form of a separate table for each institution. Note that the funding basis for the tables differs: for Howard University, revenue and expenditure data is provided in millions of dollars; revenue and expenditure data for Gallaudet University and the National Institute for the Deaf is provided in thousands of dollars.

HOWARD UNIVERSITY

(dollars in millions)

STATEMENT OF CURRENT FUND REVENUES AND EXPENDITURES
FOR FISCAL YEARS 1984 THROUGH 1993

	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
REVENUES:										
Student tuition and fees	\$32.7	\$36.5	\$39.5	\$39.5	\$49.0	\$60.5	\$65.3	\$69.4	\$74.9	\$81.6
Federal appropriations	156.2	158.2	157.1	170.2	172.2	178.9	182.4	195.2	212.3	194.0
Federal funding*	149.2	155.8	150.6	150.6	170.2	175.8	179.2	186.3	184.8	183.3
Governmental grants and contracts	4.5	4.5	5.9	5.9	3.7	3.5	3.0	3.2	4.2	4.1
Gifts and private grants	0.6	0.5	0.3	0.3	0.4	0.2	0.3	0.3	0.4	0.5
Endowment income	0.6	0.7	0.9	0.9	0.8	0.7	1.1	1.1	1.0	1.0
Sales and services of educational activities	7.2	6.0	10.1	10.1	10.5	10.6	10.2	8.0	6.6	35.5
Auxiliary enterprises	7.2	8.1	8.6	8.6	8.8	10.1	13.0	16.1	16.3	17.4
Hospital	95.6	96.6	109.1	109.1	128.9	129.4	134.2	125.9	184.8	191.2
Investment Income	N/A	3.9	5.1	5.1	6.4	8.4	1.3	2.5	2.0	1.9
Other sources	5.3	4.4	1.2	1.2	2.6	2.0	4.6	6.8	0.7	0.3
Total revenues	302.9	316.9	331.3	331.3	381.3	401.2	412.2	419.6	475.7	516.8
Appropriation as % of Total Revenues	49%	49%	46%	46%	45%	44%	44%	44%	39%	36%
EXPENDITURES:										
Instruction	\$79.3	\$83.8	\$83.8	\$86.6	\$90.4	\$97.2	\$107.6	\$109.7	\$107.7	\$109.8
Research	1.8	1.3	4.9	4.6	4.4	5.2	5.1	7.3	4.8	3.6
Public service	12.2	11.7	13.3	12.9	13.0	13.5	14.2	14.0	15.4	41.9
Academic support, including library	13.7	15.1	13.1	13.0	13.4	15.5	18.6	20.0	16.1	15.0
Student services	11.2	12.0	11.6	10.4	11.6	12.8	13.5	14.9	13.4	14.7
Institutional support	28.9	31.6	36.5	36.6	33.8	42.6	38.1	40.5	38.2	38.8
Operation and maintenance of plant	17.7	18.4	29.2	23.9	23.7	24.9	27.3	26.3	25.2	25.2
Auxiliary enterprises	12.2	14.6	9.3	8.0	9.1	10.0	12.5	15.7	13.7	13.7
Scholarships and fellowships	4.0	4.3	4.8	5.9	6.8	7.5	9.2	10.3	11.7	13.2
Transfers (nonmandatory)	0.6	6.1	4.4	7.2	(5.9)	9.2	4.0	2.6	7.2	12.7
Hospital	107.5	116.5	126.6	134.6	148.2	166.4	170.2	148.3	204.8	215.9
Debt service	3.3	1.9	1.4	3.0	3.3	4.1	13.8	7.9	9.4	12.2
Total expenditures	292.4	317.3	338.9	346.7	351.8	408.9	434.1	417.5	467.6	516.6

* Federal funds actually received.

SOURCE: Howard University

GALLAUDET UNIVERSITY ¹Statement of Current Fund Revenues and Expenditures
for Fiscal Years 1994 through 1993
(\$ in 000s)

	<u>FY 1984</u>	<u>FY 1985</u>	<u>FY 1986</u>	<u>FY 1987</u>	<u>FY 1988</u>	<u>FY 1989</u>	<u>FY 1990</u>	<u>FY 1991</u>	<u>FY 1992</u>	<u>FY 1993</u>
REVENUES:										
Student tuition & fees	\$2,843.5	\$3,567.2	\$4,204.2	\$5,340.5	\$5,981.4	\$6,547.1	\$8,745.1	\$8,984.8	\$8,422.8	\$9,870.7
Federal appropriation	56,000.0	58,700.0	59,334.0	62,000.0	61,238.0	65,010.0	68,657.0	68,845.1	73,040.0	74,152.0
Federal grants & contracts	1,967.0	1,977.7	2,462.6	2,961.8	3,896.1	4,423.6	4,003.9	3,575.9	4,714.3	4,556.4
Gifts & private grants	857.1	663.2	600.9	444.1	672.2	1,044.2	1,254.4	310.8	665.5	614.9
Endowment income	134.6	153.3	246.6	376.7	572.3	962.7	1,224.9	1,012.1	925.4	1,174.4
Other interest income	792.1	820.8	660.2	396.1	379.4	292.4	371.2	402.1	328.7	517.0
Other sources	1,150.0	1,267.5	1,435.7	1,464.6	2,047.5	3,227.3	2,280.6	1,660.8	1,630.0	1,385.7
Auxiliary enterprises	4,734.2	5,419.0	5,970.2	7,038.8	7,404.1	8,359.9	8,494.6	8,900.6	9,219.3	10,419.9
Total revenues	68,478.7	72,568.6	74,914.4	80,022.7	82,191.0	89,867.2	91,031.6	93,692.1	98,946.0	102,691.0
Appropriation as a % ² of Total Revenues	82%	81%	79%	77%	75%	72%	73%	73%	74%	72%
EXPENDITURES:										
Instruction	\$18,770.6	\$20,795.9	\$22,085.1	\$23,493.8	\$26,289.3	\$29,097.5	\$32,589.0	\$32,482.9	\$35,271.7	\$35,945.8
Sponsored research	651.8	597.0	608.3	858.1	956.9	1,259.6	1,196.7	812.4	828.9	1,064.1
Other separately budgeted research	2,565.6	2,689.6	2,520.5	2,778.0	2,713.3	2,908.9	3,050.0	3,145.6	3,570.5	3,588.3
Public services	3,074.2	3,188.4	3,864.9	3,690.2	3,962.0	6,495.5	4,764.4	4,715.0	6,110.0	5,892.4
Academic support	6,111.9	8,287.5	6,617.3	6,835.8	6,535.5	7,454.7	7,989.8	9,418.8	10,091.5	9,490.9
Student services	8,663.2	9,396.4	10,017.0	9,987.5	10,131.4	11,968.0	11,357.4	12,464.0	13,223.9	13,043.5
Institutional support	9,460.5	9,774.5	11,233.4	13,169.3	13,415.3	10,832.8	10,108.5	10,060.6	11,258.9	10,914.7
Operation & maintenance of plant	9,722.8	7,811.2	7,546.4	7,612.7	7,310.7	7,754.9	7,065.2	7,034.7	7,545.4	7,355.7
Auxiliary enterprises	3,845.0	6,523.4	6,981.0	7,956.0	6,923.6	7,939.0	7,702.5	7,869.9	8,792.6	9,059.2
Total expenditures	62,865.7	69,044.0	71,473.9	76,381.6	78,238.2	86,710.9	85,823.6	88,003.9	96,693.3	96,364.6

¹ Source: Gallaudet University audited financial statements.² The total revenue figure excludes funds received for the Federal endowment grant program, interest from Federal endowment funds, and Federal construction funds. The total income figures also treat revenue from other Federal sources as non-Federal revenue for the purpose of this calculation, including research grants and contracts, student financial aid, and vocational rehabilitation payments.

NATIONAL TECHNICAL INSTITUTE FOR THE DEAF

Statement of Current Fund Revenues and Expenditures for Fiscal Years 1994 through 1993 (\$ in 000s)

	<u>FY 1984</u>	<u>FY 1985</u>	<u>FY 1986</u>	<u>FY 1987</u>	<u>FY 1988</u>	<u>FY 1989</u>	<u>FY 1990</u>	<u>FY 1991</u>	<u>FY 1992</u>	<u>FY 1993</u>
REVENUES:										
Tuition, room, board & fees	\$4,546.6	\$5,380.6	\$5,900.0	\$6,191.3	\$6,500.0	\$6,678.8	\$6,890.2	\$7,518.4	\$8,191.1	\$8,783.0
appropriation ¹	28,000.0	30,000.0	30,624.0	32,000.0	31,403.0	33,128.0	34,384.0	36,883.5	39,097.0	40,025.0
Other sources	362.2	341.0	293.9	297.2	305.2	432.9	509.8	583.7	620.3	818.5
Endowment income ²	7.9	12.3	20.6	25.1	36.1	81.8	114.5	131.9	147.2	189.1
Total revenues	32,916.7	35,733.9	36,838.5	38,513.6	38,244.3	40,321.5	41,898.5	45,117.5	48,055.6	49,815.6
Appropriation as a %³ of Total Revenues	86%	85%	84%	84%	83%	83%	83%	83%	83%	82%
EXPENDITURES:										
Compensation	\$17,516.5	\$18,672.2	\$19,156.1	\$20,417.1	\$21,098.9	\$21,789.4	\$23,561.6	\$25,645.8	\$26,763.3	\$27,536.8
Institutional services ⁶	10,563.9	11,139.8	10,950.8	11,201.1	12,081.9	12,378.7	12,576.2	13,950.5	15,150.9	15,331.6
Capital/maintenance	1,037.2	2,233.0	2,770.0	2,777.7	269.6	1,110.6	153.0	422.7	1,030.9	318.6
Other	3,429.0	3,335.6	3,647.1	3,795.4	4,452.6	4,328.1	4,983.5	4,382.8	4,343.0	5,630.9
Total expenditures ⁸	32,546.6	35,380.6	36,524.0	38,191.3	37,903.0	39,806.8	41,274.2	44,401.9	47,288.1	48,818.0

¹ NTID does not normally show "other sources" separately. These accounts are carried as contra expenses and are netted against the expense accounts which they offset in the individual departments, i.e., income from the Education Specialist Program, theater box receipts, hearing aid shop repairs/sales, etc.

³ The endowment income is used for scholarships and aid to offset the cost of tuition, room, board, and fees for students.

⁴ NTID does not include "other sources" revenue or endowment income in its calculation of the Federal appropriation as a percent of total budget.

⁵ Compensation includes all salaries and benefits.

⁶ Institutional services includes payments made to RIT for services such as the operation of dormitories, dining facilities, physical plant services, and overhead.

⁷ Capital/maintenance includes expenditures for equipment and maintenance of buildings.

⁸ The "Other" category includes expenditures or such things as interpreting services purchased from the community, travel, supplies, telephone, faculty/staff recruitment, and grant-in-aid for students.

Total expenditure are less than total revenue as costs related to the revenue lines "other sources" and endowment funds are excluded.

TERMINATION OF FUNDING FOR NATIVE HAWAIIAN PROGRAMS

Question. Why does the Department zero out funding for Native Hawaiian programs?

Answer. The Native Hawaiian programs authorized by Title IV of P.L. 100-297 are proposed for termination for several reasons, including the following:

- o Native Hawaiians, to the extent that they meet eligibility criteria that are applied to all citizens, are eligible for Department of Education services, including student financial aid programs, that duplicate many of the activities in the Education for Native Hawaiian programs.
- o Under the 1995 budget request, the State of Hawaii will receive formula grants from such programs as Title I, Eisenhower Professional Development, and Special Education. The amount of funds going to the State is computed taking into account all students in the State, including Native Hawaiians, who are eligible for the services.
- o Several other provisions of the authorizing legislation involve activities or roles that are inappropriate for the Department of Education. For example, funds for the most part must be awarded on a noncompetitive basis to specified grantees.

Similarly, the administration's proposed reauthorization of the Drug-Free Schools and Communities Act does not include a set-aside for drug and violence prevention programs for Native Hawaiians, because the State of Hawaii would continue to receive funds, and Native Hawaiian children would continue to receive services, under the Safe and Drug-Free Schools and Communities State Grant program. Native Hawaiian organizations would also be eligible to compete for discretionary grants under the Safe and Drug-Free Schools and other Department of Education programs.

FUNDING HISTORY OF NATIVE HAWAIIAN EDUCATION PROGRAMS-- FISCAL YEARS 1989-1995

Question. Insert a table showing all programs directed to Native Hawaiians for fiscal years 1989 to 1995.

Answer. The information follows, with budget authority shown in thousands of dollars:

NATIVE HAWAIIAN FUNDING HISTORY
(Budget Authority in thousands)

<u>Program</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u> <u>Request</u>
Public Law 100-297, Title IV:							
Model Curriculum	\$395	\$494	\$521	\$450	\$416	\$50	---
Family-Based Centers	1,778	2,765	2,782	3,300	3,472	5,000	---
Higher Education	1,482	1,679	1,615	1,250	1,152	1,174	---
Gifted and Talented	790	741	864	950	992	1,000	---
Special Education	494	741	584	450	416	1,000	---
Carl D. Perkins Vocational Education Act	2,162	2,184	2,203	2,501	2,561	2,545	\$2,497
Library Services and Construction Act	612	605	615	603	603	604	515
Drug-Free Schools and Communities Act	695	1,067	1,133	1,140	1,131	1,094	---
National Institute on Disability and Rehabilitation Research, Hearing Loss Assessments	<u>500</u>	---	---	---	---	---	---
TOTAL	8,908	10,276	10,317	10,644	10,743	12,467	3,012

SCHOOL FINANCE EQUALIZATION ASSISTANCE

Question. The President's fiscal year 1995 budget includes \$8 million to help States equalize funding across districts. Isn't this a State responsibility?

Answer. The ultimate responsibility for ensuring equitable school funding within each State belongs to the States. However, the Federal Government can play a valuable supporting role by providing technical assistance to States and other interested parties on how they can improve within-State equity. Federal funds for equalization assistance could support:

- o development and dissemination of models and materials to help States construct more equitable funding systems;
- o developing model approaches to challenging issues such as how to adjust for differences in student needs and differences in the cost of education;
- o research and analysis of equity in terms of the quantity and quality of resources available at the school level; and
- o research on States' progress in moving towards greater equity.

Some equity advocates have recommended that the Federal Government condition Federal education grants on State compliance with a set of Federal equalization standards. We are concerned that this approach would intrude too heavily on States' rights, and could also end up reducing resources for poor school districts. Our proposal recognizes that each State's educational environment is unique and that there is probably not one single school finance system that would best serve all States. Therefore, we believe that providing information and technical assistance to States would be the best way to foster equal educational opportunities for all children.

DRUG ABUSE PREVENTION EDUCATION-- COMPREHENSIVE PROGRAM MODEL

Question. It has been argued that a common reason for lack of success in past prevention efforts is the inadequate use of empirically grounded theory in program development. Three of the most popular prevention approaches are affective education, life skills, and resistance training. Programs based on the affective model appear to have little impact on drug use. Programs focusing on social influences, such as peer resistance training or attempts to change perceived norms about drugs, show more promise. Comprehensive programs--programs that include a broad range of prevention strategies--have had consistently positive results. Is Drug-Free Schools funding being used for activities based on the affective education model?

Answer. Drug-Free Schools and Communities funds are being used to support all of the types of activities you have described. I agree with you that comprehensive strategies hold the most promise for success. For this reason, the

Department consistently advises schools and communities to implement comprehensive prevention programs, and the administration's reauthorization proposal for Drug-Free Schools and Communities would require that local educational agencies develop a comprehensive plan for drug and violence prevention.

16 Question. How widespread is the development of comprehensive strategies to combat alcohol and drug use with Drug-Free Schools funding?

Answer. Schools and communities throughout the country are implementing comprehensive programs. However, too often--usually due to budget constraints, sometimes due to lack of leadership at the local level--too few prevention activities are offered in a given school or community to constitute a comprehensive program.

VIOLENCE PREVENTION IN SCHOOLS-- COMPREHENSIVE EDUCATIONAL PROGRAM MODEL

Question. We know that violence is a problem in many schools. Do we know what works in violence prevention, and do we know what doesn't work?

Answer. Preventing violence is a very complex issue. As in drug prevention, there is no single "program" that will work. Rather, in order to be effective in preventing violence, schools need to develop multiple strategies that employ the resources of the entire community. Such a comprehensive approach should include, at a minimum, conducting a needs assessment; establishing and enforcing a code of conduct that includes "zero tolerance" policies related to violence and possession of weapons, and developing alternative disciplinary sanctions, besides suspension and expulsion, for students who violate these policies; educating parents and other members of the community about school safety issues and strategies, and actively involving them and students in policy and program development; developing and implementing curricula; training school personnel; improving school security, which may include adding security guards and installing metal detectors; providing students with skills, such as conflict resolution, peer mediation, and anger management, to resist engaging in violent behavior; and coordinating school-based activities with law enforcement, judicial, health, social service, and other related efforts in the community. What we know doesn't work is a singular solution, such as the simple installation of metal detectors, in the absence of a comprehensive approach.

ADMINISTRATION'S SAFE SCHOOLS PROPOSAL AND THE SAFE SCHOOLS ACT

Question. What will the \$100 million requested in the budget for Safe Schools buy?

Answer. Under the Department's original budget, not less than \$95 million would have been awarded to local school districts for a variety of services and activities that are part of comprehensive violence prevention programs, including:

improving needs assessments; coordinating school-based programs with law enforcement, judicial, health, social service, and other appropriate agencies and organizations; training school personnel in how to implement programs of conflict resolution, peer mediation, and peer resistance skills development; increasing parental efforts to promote school safety and prevent school violence; educating the community about school safety issues and strategies; developing and implementing innovative violence prevention curricula; providing alternative after-school programs that provide safe havens for students; and acquiring and installing metal detectors and hiring security personnel. Up to \$5 million would have been retained at the Federal level for national leadership activities such as research, program development and evaluation, data collection, public awareness activities, training and technical assistance, and dissemination of information on successful projects.

Subsequent to the release of the President's 1995 budget request, Congress enacted the Safe Schools Act, which provides for only one round of grants. In light of this development, the Department will revise its 1995 budget request for this program.

FEDERAL EXPENDITURES FOR DRUG ABUSE RESISTANCE EDUCATION PROGRAMS USING LAW ENFORCEMENT PERSONNEL

Question. How much money is currently being expended both within the Drug-Free Schools account and the Department of Justice for programs such as DARE, which use law enforcement personnel in drug prevention and education?

Answer. The total the two Departments are spending on programs like DARE (drug abuse resistance education) is not known. Governors are required by law to spend at least 10 percent of their Drug-Free Schools and Communities State Grant funds on programs like DARE; for 1994, this comes to \$9.1 million nationally. However, many Governors are spending more than the minimum 10 percent, and many State and local educational agencies (SEAs and LEAs) also are using their Drug-Free Schools funds for DARE-type programs.

In 1994, the Department of Justice is spending \$1.2 million to support five regional centers that provide training to police officers who provide instruction in DARE. In addition, many States use their Department of Justice (Edward Byrne Memorial) formula grant funds to pay the cost of bringing these officers into the classroom to implement DARE programs. In 1993, the most recent year for which data are available, States used \$4.5 million of their Byrne Memorial formula grant funds for DARE.

EFFECTIVENESS OF THE "DARE" PROGRAM

Question. How effective is the DARE program?

Answer. The most effective drug prevention programs are those that address the variety of factors that cause youth to engage in drug or alcohol use. The DARE program is not a comprehensive program. It offers a limited amount of

instructional material implemented over a limited number of weeks. In order to be effective, individual programs like DARE must be made part of a larger, more comprehensive strategy. DARE programs should be linked with other drug and alcohol prevention programs and strategies in order to be effective. Drug use is a complex issue to which there are no simple solutions. To be effective, prevention programs must start early, continue throughout the academic life of a child, and be supported by the efforts of family, peers, and community groups.

Question. Does the Department support earmarking a portion of Drug Free Schools funding for DARE?

Answer. No. The Department favors preserving State and local flexibility in the use of Drug-Free Schools and Communities funding for this activity.

VOCATIONAL REHABILITATION STATE GRANTS-- PROPOSED BUDGET INCREASE

Question. Why are you requesting only a small increase--\$55.3 million, or 2.8 percent, the minimum required by law--for Vocational Rehabilitation State Grants?

Answer. An increase of 2.8 percent for the Vocational Rehabilitation (VR) State Grants program is requested to help ensure that States have sufficient funds to maintain the current level of services. The requested increase satisfies the statutory requirement to provide an increase in funding at least equal to the percentage change in the Consumer Price Index for Urban Consumers over the past year.

The 1992 Amendments to the Rehabilitation Act emphasize the empowerment, economic self-sufficiency, and inclusion of individuals with disabilities; and strengthen the priority on serving individuals with the most severe disabilities. Consistent with this emphasis, the Department has requested significant increases for Supported Employment State Grants, Centers for Independent Living, and Technology Assistance programs. These programs have the potential to make a significant contribution in enabling individuals with severe disabilities to participate in education, employment, and the larger community.

We do not believe that increases in excess of the required level should be requested for the Vocational Rehabilitation program until we can better assess program performance and effectiveness. The Department is in the process of developing evaluation standards and performance indicators for the VR program. The 1992 Amendments require that the standards and indicators be published by September 30, 1994.

SPECIAL DEMONSTRATION PROGRAMS FOR PROVIDING TRANSITIONAL REHABILITATION SERVICES TO YOUTHS WITH DISABILITIES

Question. The Department proposes to increase funding for Special demonstration programs by \$2 million. The Department intends to use the

increased funding for programs to establish model systems of comprehensive rehabilitation services and job training for children with serious emotional disturbance (SED).

As you are aware, the Center for Mental Health Services administers the Children's Mental Health Services (CMHS) program. In fiscal year 1994, Congress appropriated \$35 million for this program to help States develop and operate comprehensive, community-based mental health services for children with SED.

COMPARISON OF REHABILITATION SERVICES ADMINISTRATION AND CENTER FOR MENTAL HEALTH SERVICES PROGRAMS

Why have two administrative budgets administering separate programs that serve the same population and accomplish the same goal?

Answer. In fiscal year 1995, the Rehabilitation Services Administration (RSA) proposes using the increased funding for a priority to provide transitional services for youths and young adults with serious emotional disturbance or serious mental illness. The purpose of this priority is to support demonstration projects that develop model systems of comprehensive service delivery to youths and young adults, ages 17 through 26. Projects must provide job training services to prepare them for entry into the labor force.

The RSA proposal is directed toward providing vocational rehabilitation services. Activities may include job search assistance; on-the-job training; job development, including worksite modification and use of advanced learning technology for skills training; dissemination of information on program activities to business and industry; and followup services for individuals placed in employment.

The CMHS provides comprehensive community mental health services for children and adolescents with serious emotional disturbance. Grants support a broad array of community-based and family-focused services for children with serious emotional, behavioral, or mental disorders to enable communities to develop coordinated, local systems of care that involve mental health, child welfare, education, juvenile justice and other agencies, as appropriate.

The RSA projects would provide job-training for individuals with disabilities, between the ages 17 and 26, and prepare them for employment through the provision of vocational rehabilitation services. The CMHS program is limited to those individuals under 22 years of age and funds only mental health services. Grants awarded under the CMHS program are required to support projects that provide for multi-disciplinary services to children, but grant funds may not be used for vocational rehabilitation services.

STATE POSTSECONDARY REVIEW PROGRAM--STATE STANDARDS

Question. Critics charge State Postsecondary Reviews (SPREs) will unfairly regulate tuition, curriculum, and other campus matters. What assurances can the Department offer colleges and universities in response to these concerns?

Answer. I can assure the higher education community that the State Postsecondary Review (SPRE) Program does not authorize States to set capricious or intrusive standards. In reviewing these standards, we at the Department will take special care to ensure the elemental fairness of these State standards. I should also say that we have involved the community in the overall development and implementation of the SPRE program to hear their concerns and attempt to find solutions. To that end, we held two negotiated rulemaking sessions, six regional meetings to discuss the notice of proposed rulemaking we published on January 24, and several other meetings with representatives of the higher education community. We believe that the final product will be a better one as a result of this extensive participation by the community.

PELL GRANT ELIGIBILITY INCOME CUT-OFF

Question. What is the maximum income eligibility cut-off under current law for a Pell Grant?

Answer. The Pell Grant authorizing legislation does not provide for an absolute income threshold for eligibility. The maximum income for grant eligibility for a typical family this year is about \$34,000. A "typical family" for purposes of calculating the maximum income for Pell Grant eligibility is a family of four that files a joint Federal income tax return, has no unusual family or financial circumstances, and includes one student attending a postsecondary institution.

WAIVER OF STUDENT LOAN DEFAULT RATE SANCTIONS

Question. H.R. 4025 would extend the waiver to July 1, 1998, to protect historically Black colleges and universities and certain Indian community colleges from default rate triggers cutting off schools' eligibility for the guaranteed student loan program. Does the Department support the extension of this waiver?

Answer. Yes, the Department does support the extension of this waiver.

HISPANIC PARTICIPATION IN TITLE III

Question. Hispanic participation in higher education remains low compared to participation rates among whites. In light of this gap, why doesn't the budget for Title III programs contain funds for the newly authorized program to strengthen institutions with Hispanic enrollment of 25 percent or more?

Answer. The Department has not requested funds for the newly authorized program to strengthen Hispanic-serving Institutions (HSIs), as HSIs already

compete successfully for Title III awards under the Part A--Strengthening Institutions program. In fiscal year 1993, 11 percent of the total funding awarded under the Part A program was awarded to HSIs. This represents the second highest percentage for grant awards under Part A to any ethnic group. Overall, 26 of the Nation's 125 eligible HSIs received support. In the past, it has been our experience that specific reserved funding, such as authorized for HSIs by Section 316, inhibits, rather than expands, opportunities. It was for this same reason that the Department recommended, and the Congress accepted, the Department's proposal to remove the set-aside in the statute for community colleges.

In addition to the Part A funding, Hispanic students benefitted substantially from Federal student financial programs, particularly the Pell Grant program. During 1989-90, 29 percent of all postsecondary students received Title IV student financial aid, compared with 40 percent of Hispanic students. In addition, 20 percent of all students received Pell Grants, while 33 percent of Hispanics received Pell Grants. In light of this, the Department's fiscal year 1995 budget proposes funds to support a record number of Pell Grant recipients and increase the maximum Pell Grant award to \$2,400.

In the long term, however, to increase the participation of Hispanics--and all disadvantaged students--in higher education, we need to improve the quality of the preparation they receive at the elementary and secondary level. This issue is being addressed by the administration through the recently enacted Goals 2000: Educate America Act and the Department's proposals to reauthorize the Elementary and Secondary Education Act.

GOALS 2000 EDUCATION REFORM BUDGET REQUEST

Question. How did the Department arrive at its \$700 million request for the programs authorized by the Goals 2000: Educate America Act. Please describe the specific activities that these funds would be used for at the Federal, State, and local levels.

Answer. Goals 2000 is the first Federal effort aimed at upgrading the quality of education for all students in all 85,000 public schools in America's 15,000 school districts. It is built on several hard-learned lessons from the past decade of education reform:

Education Reform Strategies

- o First, we know that the most essential step to improving what students learn is to have clear and challenging academic standards that define what we want all students to know and be able to do.
- o Second, these standards must then become the focal point for all other parts of a comprehensive and well-integrated approach to education reform--one that simultaneously improves curriculum and instructional resources; enhances the preparation and training of teachers and improves

the quality of teaching; increases parental involvement in education and strengthens support for student learning throughout the community; and increases the use of high performance management practices, so that schools are held accountable for the results they achieve, and are provided the tools and flexibility they need to determine how best to achieve them.

- o Third, education reforms must occur on a bottom-up basis, in which educators, parents, and others in each school work together to determine the steps necessary for that school to take in order for its students to reach challenging academic standards. However, to be lasting and widespread, education reform cannot be undertaken only on a school-by-school basis. We already have plenty of experience at creating individual schools that are islands of innovation, in the midst of State and local systems of education that reward mediocrity and preserve the status quo. If we are to help all students--not just those in a few model schools--reach challenging standards, we must change State and local education systems, as well as the individual schools within them.

Amount of the Goals 2000 1995 Budget Request

The funds we are requesting in fiscal year 1995 are needed to support these strategies. With \$700 million in the Goals 2000 budget we will begin with a critical mass of schools, right away, that are initiating significant education reforms aimed at helping their students reach challenging academic standards. While the amount of funds allocated to each school will be determined by States and local school districts rather than by the Federal Government, we estimate that the average award per school in the first year will be approximately \$35,000. This means that approximately 20,000 schools, or nearly one quarter of the elementary and secondary schools in the Nation, could be involved in developing their own comprehensive reform strategies during fiscal year 1995.

Local School Activities

These schools will use the funds for a variety of purposes, such as: upgrading their curriculum; helping to prepare teachers to teach new material in new, more engaging ways; helping parents better understand and become involved in achieving the new expectations for their students; networking with educators in other schools in order to learn about successful approaches; or acquiring new technologies or software that can provide powerful new tools for teaching and learning. Each school receiving Goals 2000 funds will be free to determine how best to use its funds, in the context of a comprehensive plan for helping all of its students reach the standards.

School District Responsibilities

Reaching a critical mass of schools early on is important for ensuring that reforms are widespread, rather than isolated in a few schools in each community or State. It is also important for individual school reforms to take place in the context of local districtwide and statewide reform strategies. Otherwise, even

successful schools may wind up fighting to sustain their efforts in systems that fail to provide the incentives and support for continued improvement. Therefore, Goals 2000 provides that a small share of the funds received by a local educational agency (no more than 15 percent) be used for the development and implementation of a districtwide improvement plan.

Each participating LEA must have a plan for supporting individual school reforms, and spreading them throughout the district. For example, districts will be expected to support the development or acquisition of curriculum materials that are geared to the challenging standards students are expected to achieve. They will be expected to mobilize the entire community, including parents, business, community-based organizations, and agencies providing health and social services, into a coordinated effort to support learning. They will be expected to address such issues as how they will recruit, support, evaluate, and reward teachers in order to create an effective and professional workforce, capable of helping all students reach challenging academic standards.

State Responsibilities

Participating States must also develop comprehensive, statewide education reform strategies. In order to participate in Goals 2000, a State must agree to establish challenging academic standards for all students, and to make a series of carefully coordinated changes in the State's assessment program, teacher preparation and licensure requirements, accountability system, and other aspects of the education system. And they must have a strategy for using Goals 2000 funds, as well as other Federal and State funds, to engage all schools in the State in the reforms necessary so that schools can help students reach the academic standards.

The Federal Role

The Federal Government will support these efforts in several critical ways. It will create national models of challenging academic standards that can be used, on a voluntary basis, to inform the development of academic standards in States. It will support a newly established National Education Standards and Improvement Council, which will provide broad-based oversight of the development of national standards. And it will support State and local efforts to develop new ways of measuring student performance against the standards.

Most of the funds for Title III of Goals 2000 will be used to provide seed and reform funds to States, districts, and individual schools, enabling them to undertake the necessary changes required for schools to help students reach the standards. However, the Secretary is authorized to reserve up to 5 percent of the Title III funds for national leadership activities, such as research, development, and technical assistance.

Finally, the Secretary will use approximately half these national leadership funds to support local reform activities directly, in urban and rural school districts that enroll significant proportions of students from disadvantaged backgrounds.

IMPACT OF TECHNOLOGY ON EDUCATIONAL ACHIEVEMENT AND ROLE OF DEPARTMENT IN EXPANDING USE OF TECHNOLOGY

Question. During your January visit to Iowa, Secretary Riley, you observed an impressive demonstration of the Iowa Communications Network which links high schools, community colleges, and other colleges and universities. This shows the endless possibilities of technology and education.

How important do you believe technology is in helping children achieve high standards and, particularly, what do you see the Department's role in this project?

Answer. I believe that technology, especially telecommunications technologies that deliver interactive instruction to broad areas of our States and Nation, can have a vital role to play in helping children achieve high standards. This is being demonstrated by the Star Schools projects supported by the Department. In one of those projects--the Iowa Distance Education Alliance (IDEA)--fiber optics technology is used to enable teachers to interact with students miles beyond the boundaries of their classroom. This is especially important in subject areas, such as math and science, where the supply of top quality teachers is limited, and in areas where smaller schools often cannot provide courses. Not only do students benefit, but teachers and administrators are provided the opportunity to use new approaches to instruction and see immediate results with students they could not reach without the technology.

The Department's role in technology efforts such as the Iowa project (and other Star Schools distance education projects) is to provide seed money to get large scale telecommunications projects up and running to the point they can deliver services and demonstrate the effectiveness of technology in helping us reach the Nation's education goals. While the Department provides the seed money, an essential element in this approach is stimulating the development of partnerships that can develop the resources needed to continue these efforts after the Federal support ends. The Department also provides an electronic network for the exchange of information and ideas among federally funded distance education projects. The real benefit, of course, accrues to the students who learn more effectively and have a broader selection of opportunities for learning.

IMPORTANCE OF PARENTAL INVOLVEMENT IN EDUCATION-- FAMILY INVOLVEMENT CAMPAIGN

Question. In your recent State of American Education address, you announced that the Department will launch a new initiative to encourage parental involvement in education. With all the emphasis on parental involvement in your various programs, why did you focus on this area?

Answer. Virtually everyone connected with schools agrees that it is important for parents to be involved in their children's education. Even so, all evidence shows that while schools have reached out to parents, they still have far to go to engage them actively in their children's education. Moreover, research indicates that parents want to be more involved, but often do not know how. Under the

administration's GOALS 2000 and Elementary and Secondary Education Act reauthorization bills, partnerships between parents and schools are key to the success of larger education reforms. As part of a reauthorized Title I program, for example, all schools receiving Title I funds would be required to enter into compacts with parents that spell out mutual goals, expectations, and responsibilities to help children reach challenging standards.

FAMILY INVOLVEMENT CAMPAIGN-- BUILDING SCHOOL-PARENT PARTNERSHIPS

Question. What will this initiative entail?

Answer. The Department's new "family involvement campaign" will help school-parent partnerships find wider support within communities. To launch the initiative, the Department will:

- o Create a national media campaign to promote better relations between home and school, working with organizations of parents, teachers, and principals;
- o Publish a book of "Riley's Rules," with practical advice for parents on how to help their children learn, as well as a compilation of lessons learned from examining parental practices around the world; and
- o Collaborate with other agencies, including HHS, Justice Labor, and HUD, on ways to help all adults, not just parents, "reconnect" with school-age children.

LIBRARY UTILIZATION RATES

Question. Senator Bumpers pointed out that while many of our schools and communities have fine library facilities, no one uses them. Does the Department have any data on library utilization rates that would support this assertion?

Answer. What Senator Bumpers reports may be a relatively isolated situation. The National Center for Education Statistics reports the results of a an annual national survey of public libraries in its publication *Public Libraries in the United States*. These reports show steady growth in public library use since 1989, the first year for which survey results were reported. The most recent report, of data from 1991, shows that total nationwide circulation of library materials was over 1.4 billion or 6.1 per capita of legal service area population. This represents a slight increase over 1990's circulation level of not quite 1.4 billion or 5.75 per capita and 1989's of not quite 1.4 billion or 5.60 per capita. In 1991, libraries reported that the public asked over 222 million reference questions, compared with over 201 million in 1990 and almost 182 million in 1989.

The Roles of the Public Library in Society--The Results of a National Survey, a 1992 study by the University of Minnesota in concert with the Gallup Organization, found that Americans view the public library as a key educational

institution. The survey asked a national sample of the general public to evaluate the importance to their communities of the major roles of the public library. The top-ranked roles were:

- o educational support center for students of all ages (88 percent);
- o learning center for adult independent learners (85 percent); and
- o discovery and learning center for preschool children (83 percent).

Findings also indicated that the lower the education and income level of the public, the higher they rate the educational importance of their public library. These findings are supported by a 1991 household survey conducted by the National Center for Education Statistics which found that 42 percent of African Americans interviewed said they had used a public library in the last year; 32 percent of Hispanics said they had used a library, as did 55 percent of whites and 52 percent of all others.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

OUNCE OF PREVENTION PROGRAM

Question. The most recent data on births among adolescents indicate that the teen birth rate in 1991 continued the rise that began in the late 1980s. Between 1986 and 1991, the rate of births to teens aged 15-19 rose 24 percent, from 50.1 to 62.1 births per 1,000 females aged 15-19.

Secretary Riley, in your letter of March 11, 1994, you refer to the Ounce of Prevention program. Would you explain to the Committee how this program operates and its funding source?

Answer. The Ounce of Prevention program is included in both the Senate and House versions of the Crime Bill. The Senate version would establish an Ounce of Prevention Fund and authorize \$75 million for the program. The program would be administered by the Ounce of Prevention Council, which would be chaired by the Attorney General and the Secretaries of Education and Health and Human Services. The program would support discretionary grants in high poverty areas for after-school and summer programs, mentoring, and other activities involving adult role models. The Ounce of Prevention Council would also administer the Community Schools Youth Services and Supervision Grant Program. This program would provide funds to community-based organizations to offer after-school and weekend programs linked to schools. The bill provides that if the appropriation exceeds \$20 million each State would get an allocation and a competition would be established within the State; if the appropriation is less than \$20 million, the Council would conduct a competitive program.

The House version also provides for an Ounce of Prevention Council and would authorize \$25 million for the program. The Secretary of Health and Human Services, after consultation with the Council, would make grants to States, local governments, educational institutions, coalitions, local educational agencies, and State educational agencies for summer and after-school programs;

mentoring, tutoring and other programs that involve participation of adult role models; programs that promote job placement; and drug treatment and prevention programs. The House bill also provides for a Family and Community Endeavor Schools Grant Program, which would be administered by the Secretary of Education. Under this program the Secretary would be authorized to allocate to community-based organizations in each State funds based on a population formula. The community-based organization would carry out its program in a public school or another appropriate local facility. The funds are to be used for supervised sports programs and extracurricular and academic programs that are offered after school and on weekends and all day during the summer. The bill would authorize \$23 million for the program.

SUPPORTING STATE AND LOCAL EFFORTS TO REDUCE DROPOUT AND TEEN PREGNANCY RATES

Question. Your letter also mentions the Goals 2000 monies and that each community and school that is serious about readiness and decreasing drop-out rates will address, in a unique way, teen pregnancy and related issues. Does the Department plan to give States any encouragement to implement programs that will specifically address teen pregnancy prevention programs or the importance of prenatal care?

Answer. Goals 2000: Educate America Act establishes eight National Education Goals, including "readiness for school" and "increasing rates of high school completion." In addition, the Act provides a framework and support for States and communities striving to meet these Goals. Recognizing that the Federal Government does not have all the answers, the Act supports a "bottom-up," grassroots approach to school reform. The Department's role is to assist States and local communities in the development and implementation of their own comprehensive reform plans. Thus, as States and localities develop Goals 2000 plans that address the needs of their students, including strategies for reducing dropout and teen pregnancy rates, the Department will work with and support them through technical assistance and other means.

COMPREHENSIVE SCHOOL HEALTH EDUCATION PROGRAM-- INVITATIONAL PRIORITY TO ADDRESS TEEN PREGNANCY

Question. Mr. Secretary, in fiscal year 1994 when the \$4.6 million for the Comprehensive School Health Education program was competed, an invitational priority was included to focus on projects that provide comprehensive health education to students at risk of having low birth weight babies. Given the magnitude of the teen pregnancy problem and the incidence of low birth weight babies born to teens, shouldn't this have been an absolute priority in order for a grantee to successfully compete for the funds?

Answer. The fiscal year 1994 application notice for this program, containing an invitational priority, had been published in September of 1993. Following final action on the appropriation, the Department amended its application notice, adding a second invitational priority to address the teen pregnancy problem and

giving potential applicants additional time to apply for a grant. We did not believe it was necessary to cancel the already announced competition, which would have worked a hardship on those already preparing applications. High-quality applications addressing the teen pregnancy problem will be competitive.

COMPREHENSIVE SCHOOL HEALTH EDUCATION BUDGET REQUEST FOR FISCAL YEAR 1995

Question. How much is the Department planning to spend in fiscal year 1995 on the Comprehensive School Health Education program?

Answer. The Department expects to use about \$3.4 million in 1995 for continuation grants. If a new health education program is created as proposed in the administration's health care legislation and described below, we would probably not use additional Fund for Innovation in Education (FIE) funds for this purpose.

FEDERAL INITIATIVES TO REDUCE THE RATE OF TEEN PREGNANCY

Question. Should the administration and the Congress begin new programs that would specifically focus on reducing unintended teen pregnancy?

Answer. The Department is currently considering various approaches to reducing teen pregnancy including both targeted interventions and more comprehensive interventions such as mentoring, coordinated services, connections to the job market and postsecondary education, and schools as community centers. Many of these more comprehensive strategies could be supported through the Goals 2000: Educate America Act, the School-to-Work Opportunities Act, and the administration's proposal for the reauthorization of the Elementary and Secondary Education Act.

Question. What coordination exists between the Department of Health and Human Services and the Department of Education with regard to programs focused on reducing the rate of teen births?

Answer. The two Departments are collaborating on a variety of initiatives that would address reducing the rate of teen births.

The Assistant Secretary for Elementary and Secondary Education and the Assistant Secretary for Health co-chair the Interagency Committee on School Health. That committee has been a forum for joint work on health education, coordination of services, and school-based and school-linked health services.

In addition, the two Departments jointly developed two initiatives in the Health Security Act. The first is a comprehensive K-12 health education program, which will be targeted to high-poverty areas with particularly significant health problems. Our joint approach is designed to ensure the involvement of both educators and health providers at the Federal, State and local levels and to ensure the coordination of existing health education programs. The second initiative

would fund school-based and school-linked services in high-poverty areas to address the health needs of at-risk students, including nutrition, health screenings, and counseling. The two Departments are committed to continue working together as these programs are designed and implemented.

Other joint efforts include collaboration on the development of the Healthy Schools, Healthy Communities program for school-based health centers administered by the Bureau of Primary Health Care.

COST OF TEEN BIRTHS AND ROLE OF SCHOOLS IN REDUCING TEEN PREGNANCY

Question. In 1990, an estimated 51 percent of Aid to Families with Dependent Children (AFDC) payments went to recipients who were 19 or younger when they first became mothers. Based on estimates of AFDC, Medicaid, and Food Stamps support to families begun by a teen birth, teenage parenting cost the U.S. over \$25 billion in 1990, an increase of 16 percent or \$3.5 billion over 1989. According to the Population Resource Center, it is estimated that if every teen birth had been delayed until the mother was in her 20s, the U.S. would have saved 40 percent of these expenditures, or \$10.2 billion.

As the administration and the Congress work toward revamping this Nation's health care system, and the enormous task of finding ways to finance the coverage of those 38.5 million Americans without health insurance, I would think investing in programs that could reduce the costs associated with teen pregnancy is one way to save an enormous amount of money. As we examine ways to overhaul the welfare system, do you have any suggestions as to what role schools could play?

Answer. The administration is committed to a welfare reform plan that will promote parental responsibility and reduce teen pregnancy. The Welfare Reform Working Group, which includes four senior staff from the Department of Education, is currently exploring various strategies for teen pregnancy prevention, including a variety of school-based and school-linked strategies.

INTERNATIONAL COMPARISON OF TEEN PREGNANCY RATES RESEARCH

Question. Teenage pregnancy, birth, and abortion rates in the U.S. are the highest in the Western world. Unlike the U.S., teen birth rates have fallen dramatically since 1970 in much of Western Europe. For example, the United Kingdom has decreased its birth rate to teens from 49.1 percent in 1970 to 31.7 percent in 1989, while Japan's birth rate to teens has remained at a rate of approximately 3.7 percent since 1970.

Are you aware of any proven teen pregnancy programs that have been implemented in the Western European countries that can be duplicated here in the U.S.?

Answer. The Department is not aware of proven teen pregnancy prevention programs that have been implemented in the Western European countries that could be duplicated here.

Question. Can you explain the reason for the low birth rate among teens in Japan?

Answer. The Department is not aware of any research specifically on the low birth rate among teens in Japan.

RESEARCH-SUGGESTED REASONS FOR HIGH PREGNANCY BIRTH RATE AMONG TEENS IN U.S.

There has been some research on differences in pregnancy and birth rates among industrialized countries that suggests some reasons why teen birth rates are higher in the United States than in Europe. Among the reasons suggested are that the United States has: higher rates of unintended conception; lower median age of first intercourse; different social norms regarding teenage sexuality and sexual behavior; high rates of poverty; and less access to basic health and social services, including contraceptive services; as well as less confidentiality for young people seeking contraceptive services because of stricter legal requirements to inform parents or seek their consent before delivering reproductive health services to minors.

ADULT EDUCATION--PRISON EDUCATION PROGRAMS

Question. Secretary Riley, within the Adult Education Basic State Grant program, the authorizing statute requires that 10 percent of these funds, or about \$26.7 million of your budget request, must be spent for correctional education and education programs for other institutionalized individuals.

Would you tell me how much of your request do you expect to spend on correctional education?

Answer. Using reports provided by the States, the Office of Vocational and Adult Education estimates that States spend 75 percent of the set-aside funds for corrections education. The remaining 25 percent is used for education programs for other institutionalized individuals. Based on these percentages, States will spend approximately \$20 million on corrections education this year.

Question. How much of the 10 percent set-aside was spent in fiscal year 1994 on correctional education?

Answer. Based on the percentages cited above, States will spend approximately \$19 million on corrections education in fiscal year 1994.

VOCATIONAL EDUCATION--PRISON LITERACY PROJECTS

Question. In fiscal year 1991, at my direction, \$2 million was included for a prison literacy demonstration program. That demonstration has now been running for about two years. Has the Department conducted an evaluation of this demonstration program, and if not, are you planning to do an evaluation?

Answer. The Department has not yet planned an evaluation of the corrections education projects funded under Vocational Education Demonstrations.

FUNDING AND EVALUATING LITERACY PROGRAMS FOR PRISONERS

Question. Have evaluations been conducted on the funds being expended for corrections education in the vocational and adult education programs?

Answer. We plan to begin an evaluation of the Adult Education set-aside for corrections education and education for other institutionalized individuals this fall and are also considering a similar evaluation of the Perkins Act set-aside for criminal offenders.

Question. Are you requesting \$5 million for Literacy Programs for Prisoners?

Answer. Yes, our fiscal year 1995 request for Literacy Programs for Prisoners is \$5.1 million.

Question. If we are to reduce the recidivism rate in the U.S., shouldn't we be spending more in this area?

Answer. The Department will spend approximately \$49 million in fiscal year 1994 to educate inmates in correctional institutions, a sizable expenditure. Before the Department commits additional funds to this activity, we need to learn more about the effectiveness of existing programs as well as State-level efforts to serve this population. The Department is taking steps to gather this information.

PRIVATE MANAGEMENT COMPANIES--ROLE IN SCHOOL REFORM AND REQUIREMENTS AND EXPECTATIONS FOR PRIVATE CONTRACTORS

Question. Mr. Secretary, as you know, on January 25, 1994, this subcommittee held a hearing on Private Management Companies and the role these companies could play in school reform. One of the witnesses at the hearing was Benno Schmidt, President of the Edison Project. Mr. Schmidt described an Edison-run school as one which would offer a longer school year (210 days, or 30 days longer than the average American school year); which would be open from 7:00 a.m. to 6:00 p.m.; and which would have state-of-the-art technology--such as TV interactive computer instruction--and a teacher to student ratio of 17.1 (21-25:1 in urban areas such as Philadelphia). Mr. Secretary, what is your opinion of the private school management concept?

Answer. If a school district wants to hire a private company to manage its schools, it should be able to do so. Some school districts are currently "contracting out" some or all instructional services, as well as other services.

I think we should keep an open mind about this. But I also believe that private contractors ought to be required to meet the same expectations as those established for public school educators. For example:

- o The final decision to contract should be made locally, to ensure that the contract is tailored to the particular needs and resources of the school or schools involved.
- o The ultimate goal should be to improve teaching and learning to help all students reach high standards set by the State and community. This means significantly improving professional development of school staff and ensuring that students can learn in a safe and drug-free environment.
- o There should be clear goals and performance standards, and public reporting on performance and progress in attaining those standards.
- o The arrangement should be part of a comprehensive, system-wide plan to move all students toward high standards.
- o A contractor should meet civil rights requirements. All students should have equal access to participate in contractor-operated schools.
- o There should be a level playing field; per-student spending in schools contracting out some or all of their instructional services should be held roughly to the same level as in other schools in the community, and policy mandates governing public schools should apply equally to private contractors.
- o There should be proper supervision of the contract and the company's performance in carrying it out.

PRIVATE MANAGEMENT CONTRACTING UNDER GOALS 2000

Question. Do you think it is one of the ways to reform this Nation's schools?

Answer. Contracting may be one of many approaches that school districts and States wish to use in their efforts to promote comprehensive, continuous improvements in teaching and learning.

Under the Goals 2000: Educate America Act, after subgranting funds to local educational agencies, a State may use the remainder for a variety of activities designed to implement its State improvement plan. The Act specifically permits the use of these State funds to support "activities relating to the planning of, and evaluation of, projects under which local educational agencies or schools contract

with private management organizations to reform a school." At the local level, a school district could also choose to use its Goals 2000 funds for this purpose.

Contracting should to be a school improvement option for States and communities that want to use it. But it is an option that should be studied and evaluated by independent organizations that have no stake in the outcome. These evaluations can help us learn what works, under what conditions it is successful, and what does not work.

IMPACT OF COMPUTER-ASSISTED INSTRUCTION ON EDUCATIONAL ACHIEVEMENT

Question. Private management firms favor technology-based educational strategies over the more traditional teaching approaches. Do you know of any evidence that the use of computer technologies increases educational achievement?

Answer. A number of studies show that the exposure to highly structured computer-assisted instruction (CAI) results in measurable effects on student learning, as measured by standardized achievement tests. Also, well-controlled studies comparing students taught with CAI and those taught conventionally have consistently favored CAI at the elementary, secondary, and postsecondary levels (Kulik & Kulik, 1991, and Kulik, Kulik & Bangert-Drowns, 1985). Several studies conducted by the Cognition and Technology Group at Vanderbilt University reveal that the use of computer technologies (the video-based "**Jasper Series**") improves students' complex problem-solving skills. In addition, computer technologies can help students develop higher-order thinking skills (Pogrow, 1990).

FEDERAL EDUCATION FUNDING OF PUBLIC PARTNERSHIPS WITH PRIVATE, FOR-PROFIT FIRMS

Question. The Baltimore City Public Schools has formed a partnership with Sylvan Learning Systems to provide Chapter 1 instruction to 700 students in five city schools. The public/private partnership, the first of its kind to administer Chapter 1 programs, began a one-year pilot program last May. Is it appropriate for funds provided under Federal education aid programs to be used to buy instructional services from profit-making firms?

Answer. So long as there is no prohibition in the authorizing statute of the Federal program, and the expenditures comply with applicable cost principles, I can see no reason for a school not to use Federal education funds to purchase instructional services from a profit-making firm.

Question. Should such contracting be restricted to non-profit organizations, or should States and localities be free to procure services from whomever they believe will provide services most effectively?

Answer. I see no reason that such purchases should be restricted to any particular kind of organization. States and localities should certainly be free to

use Federal funds to purchase instructional services and materials from whatever firm best meets their needs.

Question. Did this contract require any regulatory waiver or special arrangements with the Department of Education?

Answer. No, we did not issue any waivers or make special arrangements to facilitate the Baltimore Public Schools' partnership with the Sylvan Learning Systems. The Department did not at that time have the authority to issue waivers of any Chapter 1 programmatic requirements.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

PACIFIC BASIN REHABILITATION RESEARCH AND TRAINING CENTER

Question. Mr. Secretary, I understand that the Department has decided to deny the third cycle of funding for the Pacific Basin Rehabilitation Research and Training Center (PBRRTC) of the Rehabilitation Hospital of the Pacific (REHAB), which was specifically authorized in the Rehabilitation Act Amendments of 1986. PBRRTC is intended to improve services to individuals with disabilities through relevant rehabilitation research and training in the Pacific Basin. PBRRTC is the only comprehensive medical rehabilitation center in the Pacific islands serving individuals with physical disabilities. This decision means that PBRRTC will have to fire 18 employees this fiscal year, thus drastically reducing its ability to serve its target population. What is the Department's justification for this action?

Answer. The Department has had every intention of continuing support for a Rehabilitation Research and Training Center for the Pacific Basin as required by section 202(j)(2) of the Rehabilitation Act. The Department announced a competition on October 19, 1993, with a closing date of November 19, 1993, so that a new award could be made before the expiration of the project period for the existing Center. Unfortunately, the application the Department received was determined not to be fundable based on the selection criteria in the regulations. Three of the five reviewers recommended that the application not be funded.

The Department reannounced the competition for the Pacific Basin Rehabilitation Research and Training Center on March 16, 1994, with an application closing date of May 18, 1994. The Department intends to expedite the selection process so that an award can be made quickly in order to provide for as much continuity as possible in carrying out the activities of the PBRRTC.

ACCESS TO REHABILITATION SERVICES IN THE PACIFIC BASIN REGION

Question. What other recourse will disabled individuals in geographically isolated areas of the Pacific Basin have in order to obtain needed rehabilitative services?

Answer. The Pacific Basin Rehabilitation Research and Training Center is not authorized to provide direct services except as a component of the Center's

research, demonstration, and training activities. Rehabilitation services are provided through a range of providers, including community rehabilitation programs, rehabilitation hospitals, and other private and public agencies. The Department provides over \$10 million to vocational rehabilitation agencies in Hawaii and the four territories for vocational rehabilitation services.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

STUDENT LOAN BORROWER DEFENSES

Question. I have a couple of questions about the draft regulations the Department has proposed to implement the Student Loan Reform Act, which we passed last year. I understand that the Department has proposed to limit the rights of the borrower to raise the fact that they were defrauded to only 18 months from the date that the loan was made. If this is correct, what is the logic for such a move, and might it not inadvertently create a big problem for some borrowers if they do not find out about the fraud until after they leave school, but the fraud occurred early in their student career? What is the legislative history that supports such a proposal?

Answer. For the first year of the Direct Loan program, students may make a claim to the Department of Education and assert a defense against the repayment of a Direct Loan based on act or omission of a school for up to 18 months after the date the loan was disbursed to the borrower. In most instances, previous defense claims have involved trade schools offering relatively short programs and, therefore, we considered 18 months to be a reasonable length of time.

For the second and future years of the Direct Loan program, the Department is currently conducting regulatory negotiations sessions with members of the higher education community and student representatives. One item being negotiated is the length of time a borrower may have to present a claim to the Department. There is no Federal precedent in the student loan programs for defense provisions and State law varies considerably. We are working closely with the higher education community to develop a standard that is fair to students and schools.

STUDENT LOAN REPAYMENT AND REAFFIRMATION RULES

Question. The draft regulations apparently also require students whose previous loans were forgiven for legitimate reasons to repay their forgiven loans if they want to obtain new loans. Is this true, and, if so, what is the logic and statutory basis for such a proposal?

Answer. For the first year of the Direct Loan program, a borrower's loan obligation is canceled in the event of death, total and permanent disability, or if the loan is discharged in bankruptcy. Further, the Department requires a borrower whose loan was canceled due to a total and permanent disability or bankruptcy to reaffirm that prior debt if the individual is seeking a new student

loan. This policy is consistent with current Federal Family Education Loan policy and is intended to prevent abuse of the system.

Loan reaffirmation regulations for the second and future years of the Direct Loan program are currently being developed in regulatory negotiation sessions with members of the higher education community and student representatives. The Department is reviewing this and other student aid provisions to ensure that the best interests of students, schools, and taxpayers are being served.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

CONSUMER AND HOMEMAKING EDUCATION-- PROPOSED TERMINATION OF FUNDING

Question. Mr. Secretary, the President's budget calls for no further funding of the Consumer and Homemaking Education program. I know the Department of Education's rationale for this cut is that the program is either duplicated, has achieved its goal, or can be funded by non-federal resources but I'd like a more detailed explanation. I am concerned that, if we don't fund this program, States will be left with the tough decision of whether or not to include this program in the curricula. While that is certainly their choice, I know how important parenting skills, child care and teen pregnancy education are to a large portion of our student population and I want to make certain that these programs are available to those who need it. If this program is zeroed out, where can schools in my State, particularly rural schools, find funding for these needs?

Answer. The National Performance Review recommended the elimination of the Consumer and Homemaking Education program specifically because the program can be more appropriately funded through non-Federal sources. For every Federal dollar spent for this program, States spend \$20 in State and local resources. Currently, all States have well-established consumer and homemaking programs that will continue without direct Federal support. States and localities can, if they choose, use funds from their Vocational Education Basic State Grants funds to support consumer and homemaking education.

While parenting, child care, and other topics often covered by Consumer and Homemaking programs are important, communities across the country have clearly demonstrated that they will provide these programs without Federal support. Even though it is nice to supplement all the State and local support with a little Federal funding, it is difficult to argue that this funding should continue under the current budget caps, when many higher-priority needs may not be met.

STATE STUDENT INCENTIVE GRANTS

Question. The State Student Incentive Grant Program (SSIG) has also been cut in the President's Budget. Given the administration's commitment to ensuring the opportunity to pursue postsecondary education to those who want it and, more importantly, the fact that these funds go to the neediest students,

I am concerned that this cut may be counter-productive. Could you elaborate on the reasoning behind this recommended cut and tell me what you would suggest to those States who will experience elimination or drastic reduction in their ability to provide postsecondary grants for students if this program is eliminated?

Answer. We believe that the SSIG program has achieved its goal as defined in the statute--through incentive grants, it has successfully encouraged States to provide need-based student financial aid. Evidence of this success is that fact that 56 States currently offer such aid, up from 26 when the program began in 1974. In addition, these States have continued to expand their need-based student aid programs even in recent years when Federal SSIG funding has decreased or remained level.

We do not anticipate that States participating in the SSIG program will decrease or eliminate their contributions. On the contrary, historical trends indicate that most if not all States will make up for the loss of Federal dollars, which make up a relatively small share of overall State need-based aid awards, and that most students will lose little or none of their awards.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

TIMETABLE FOR STATE TECHNOLOGY PLANNING AWARDS

Question. In fiscal year 1994, \$5 million was added to the \$100 million appropriated for Goals 2000 to fund State technology planning. Assuming that the Goals 2000 legislation is enacted prior to the April 1, 1994 deadline, do you have a timetable for making the \$5 million available to the States for technology planning once the bill is enacted?

Answer. Yes, we do. Since States are to request funds for State technology planning as part of their applications for first-year Goals 2000 funds, funding will be made available according to the same timetable from both sources. Fiscal year 1994 funds for State technology planning could be awarded as early as July of 1994, if the State's application for Goals 2000 is received and approved, and the State requests State technology planning funds.

EDUCATIONAL TECHNOLOGY PROGRAMS IN GOALS 2000 AND ESEA LEGISLATION

Question. Senator Bingaman and I, along with many other Senators, including Senators Harkin and Kennedy, have worked for several years on legislation designed to encourage greater use of technology in the K-12 classroom. Your staff at the Department has been very helpful in advising us on provisions of the bill. Portions of S. 1040 have been incorporated into Goals 2000, and other provisions are expected to be incorporated into the Elementary and Secondary Education Act (ESEA).

The Department of Education budget includes a request of \$50 million for Educational Technology in fiscal year 1995. Would it be appropriate to assume the \$50 million would be for programs like those included in S. 1040?

Answer. The \$50 million request in the Department's fiscal year 1995 budget was for the educational technology authority proposed by the Department as part of ESEA. The Goals 2000: Educate America Act includes a modified version of that proposal, as does S. 1040.

However, S. 1040 contains several additional provisions and programs, all of which are more prescriptive but most of which are designed to support activities that could be supported under the broader authority proposed by the administration. These additional programs include formula grants to States and districts to purchase technology and provide for connectivity and teacher training; support for regional consortia to provide technical assistance to States and districts on the use of technology and to provide professional development for educators on technology; and development of technology products and educational applications of advanced technologies and networks.

Except for formula grant support to States and districts for technology purchases, these sorts of activities could all be undertaken pursuant to the Department's request.

QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

COMBATTING YOUTH VIOLENCE IN SCHOOLS AND COMMUNITIES

Question. I would like to take this opportunity to express my strong support for reducing violence in our schools and communities as a top priority, and retaining funding for the Student Literacy/Mentoring Corps Program and Impact Aid.

During the last decade, violence in schools has increased dramatically. Statistics show that some 3 million crimes a year are committed on or very near to school campuses. More than two-thirds of all public school teachers have been verbally abused, threatened with injury, or physically attacked. One-fourth of all major urban school districts now use metal detectors at their schools. And, perhaps most significantly, almost half of all of the people who leave the teaching profession do so citing discipline problems as one of the frustrations which cause them to abandon this noble profession.

In order to help combat this increasing violence problem in our schools and to ensure a safe learning environment for our children, I added a "Youth Violence in our Schools and Local Communities" amendment to Goals 2000. This was a direct response to the concern for school discipline and the safety of students and teachers that I repeatedly heard from participants of my Washington State Education Conference held in January. Unfortunately, my amendment was struck by the conference committee. This amendment simply stated that no Federal law or regulation would restrict the disciplinary rights of school districts and of

schools regarding criminal or violent activity on the part of students on those school grounds.

My amendment had the support of the Washington State P.T.A.; the Washington Association of School Principals and their National Affiliates, the National Association of Elementary School Principals and the National Association of Secondary School Principals; the Washington State Educational School Districts; and the Washington State School Directors' Association. These groups deal with our children on a daily basis and understand the critical need of providing a safe learning environment.

We must deal decisively with violent and criminal behavior in our schools--and we must deal with it today. Violent or criminal behavior is taking place very day and it undercuts tremendously not only the security of our students, teachers, administrators, and communities, but also with equal importance the ability of the millions of our students to learn in a safe environment. The ideals of Goals 2000 cannot be met without our students, parents and teachers free from the fear of violence.

ADMINISTRATION REACTION TO PROPOSED "YOUTH VIOLENCE IN OUR SCHOOLS AND LOCAL COMMUNITIES" AMENDMENT

Would the administration consider working with me to add my "Youth Violence in our Schools and Local Communities" amendment to the reauthorization of the Elementary and Secondary Education Act later this year?

Answer. We would be happy to discuss with you the scope of disciplinary measures available under State and Federal law to school districts and schools for dealing with violent behavior on school grounds, and the types and sources of information regarding, among other things, prior convictions and pending arrests for violent offenses, that schools and school districts should have access to in order to minimize violent behavior on school premises.

We have concerns, however, with how the proposed amendment (section 803(a) of the Senate-passed version of H.R. 1804) is written. For example, it would make inapplicable to local school district and school disciplinary policies Title VI of the Civil Rights Act of 1964 (pertaining to discrimination on the basis of race, color, or national origin) and Title IX of the Education Amendments of 1972 (pertaining to discrimination on the basis of gender). We seriously question enacting such a sweeping invalidation of civil rights laws. Also, to the extent that it is deemed to be a "criminal act" for a student to bring a weapon to school, or that a school intends to discipline such a student for related criminal conduct, section 803(a) appears to be inconsistent with the more stringent requirement, already in law in Title VIII of the Goals 2000: Educate America Act, that local educational agencies expel for at least one year any student who brings a weapon to school.

IMPACT AID REQUEST FOR FISCAL YEAR 1995-- REACTION OF CLOVER PARK SCHOOL DISTRICT, WASHINGTON

Question. The President's Budget for 1995 shows major cuts in Impact Aid 3(b) payments. I am committed to ensuring a healthy and safe learning environment for Impact Aid children within the Clover Park School District and throughout Washington State. I have spoken with the Superintendent Forsys of the Clover Park School District and the President of the Clover Park PTSA and they have expressed their concern for the Federal Impact Aid funds. They claim that this cut would devastate the school district. It is the belief of the PTSA Council and community members that Federal Impact Aid must not only be continued, but increased to allow for inflation. Superintendent Forsys expressed her most urgent concern of P.L. 81-874 funding because of the number of students they serve from Ft. Lewis, McChord AFB, and the civilian community of Lakewood. She claims that without adequate 874 funds, they would have great difficulty providing educational services.

In a recent letter to me, Debbie Severe, President of the Clover Park PTSA states:

"Federal Impact Aid dollars equalize educational funding in the school district between community residents who fund education through their property taxes and military families who do not pay local property taxes but send their children to our district schools. Federal Impact Aid pays teacher's salaries; and provides books, furniture, buses, etc., items necessary to give quality education to students. However the funds have not increased with inflation and have been frozen for over nine years. Now with the arrival of more families from Germany, the need is even greater for consistent increases in Federal Impact Aid funding to meet the needs of both military and nonmilitary students."

PROPOSED TERMINATION OF IMPACT AID SECTION 3(b) FUNDING

Mr. Secretary, could you explain further the basis for eliminating funding for impact aid and, specifically, what will happen with 874 funds?

Answer. We have not proposed the elimination of Impact Aid, but we have requested no funds for section 3(b), and our reauthorization proposal would eliminate the authority for those payments. The education of "b" children is generally fully supported through the State and local tax base, because, unlike other federally connected children, "b" children are members of families who either live or work in the local community and thus contribute substantially to the local tax base. However, the significance of our reauthorization proposal goes much further than simply eliminating "b" payments.

ADMINISTRATIONS'S IMPACT AID REAUTHORIZATION PROPOSALS

Under the proposed reauthorization, the Department would provide Basic support payments for children who live on and whose parents work on Federal property, as well as children living on Indian lands. (These children are currently

referred to as "a" children.) The legislative proposal would simplify and change the formula to approximate more closely the actual local cost of educating these federally connected children.

Our budget proposal of \$694 million for the new program of Basic Support Payments, coupled with the \$45 million request for payments for children with disabilities, is slightly higher than the combined amounts appropriated in 1994 for payments for "a" and "b" children.

It is important to consider our request for the elimination of "b" payments in the context of the rest of our proposal. Our request would essentially provide an increase for "a" payments, under a revised formula that distributes funds more equitably among school districts that educate these children. Since Impact Aid is meant to supplement local funding for the education of federally connected children, the formula we have proposed would redirect "a" payments to districts that have a high average per-pupil expenditure, a relatively high share of which is provided from local revenues.

IMPACT OF REAUTHORIZATION PROPOSAL ON CLOVER PARK

Clover Park currently educates almost 4,200 "a" children and over 2,200 "b" children. Its 1993 Impact Aid payment was \$6,922,551, of which only \$93,057 was for "b" children. Under our reauthorization proposal and budget request for fiscal year 1995, Clover Park would receive \$5,815,957. The decrease in funding for Clover Park would largely be due, not to the elimination of "b" payments, but to the fact that Washington has a very strong State funding program; over 77 percent of education funds in Washington is provided from State sources, while only 23 percent is provided locally. This result is consistent with the purpose of the program, which is to supplement local funding for education, not to supplant State funds.

ASSUMPTION OF OWNERSHIP OF SECTION 10 SCHOOLS BY CLOVER PARK SCHOOL DISTRICT

Question. Superintendent Forsy mentioned that they have not had a response from your office to their offer to assume ownership of schools owned by DOE. They believe they have been "put on hold." These schools are in deplorable shape and are in need of immediate repairs or rebuilding. Is it possible for the Clover Park School District to assume ownership of these schools?

Answer. The Department has had negotiations with Clover Park, since 1991, regarding the amount of work that needs to be done before the school district will accept ownership of the seven Section 10 schools at Fort Lewis and McChord Air Force Base. The initial itemized list of repairs and renovations submitted by Clover Park amounted to \$13.5 million, well in excess of our available section 10 appropriation, without taking into account the need to reserve some funds for essential health and safety repairs of the other section 10 buildings for which we are also responsible. As a result, we advised the school that we would repair and transfer one or two buildings at a time, as funds became available.

The Department reserved funds to improve and transfer two schools at a total cost of \$4,057,527, and informed the school district of this action. Several months later, the school district made an alternative request for a funding package totalling \$6,405,032, which included tearing down a third school, replacing it, and making only minimal changes to two other schools. In August 1993, we advised the school district that our funds were insufficient to approve this request at the time and asked them to indicate whether they wished to proceed with the originally approved plan to upgrade and transfer two facilities. Clover Park then agreed to accept the two schools.

Most recently, in February 1994, Clover Park school officials made a new proposal to accept the transfer of all seven schools in return for more freedom in deciding how to use the \$4 million currently designated for Clover Park projects as well as some undetermined amount of future construction funds. We are currently reviewing this new offer.

STUDENT LITERACY AND MENTORING CORPS AND INNOVATIVE PROJECTS FOR COMMUNITY SERVICE

Question. I noticed you propose to terminate the Student Literacy and Mentoring Corps program and in its place expand the "Innovative Projects for Community Service," administered through the Fund for the Improvement of Postsecondary Education. You state on page O-36 of Volume II of your budget justification for Higher Education, the Innovative Projects may support research regarding the effects of the student community service organizations, provide assistance to student organizations that work with community service organizations, support linkages between youth corps and institutions of higher education, and/or support innovative student service programs.

While I applaud the role of these projects, I am concerned that you are suggesting we eliminate the Student Literacy and Mentoring Corps program without ensuring that similar programs will be established on America's college and university campuses. Moreover, since this program has been in place since 1989 and continues to provide quality services to disadvantaged persons across the Nation, its termination could create unnecessary duplication of paperwork for colleges and universities who have taken the initiative on volunteerism and literacy issues and established Student Literacy/Mentoring Corps programs.

In Washington State, we have 15 colleges and universities who have received funding under the program. They are striving to reach the estimated 450,000 Washington State residents who are considered functionally illiterate. I would like to share with you a letter I received from those 15 institutions which describes, in some detail, the benefits this program has had for Washington State and the detrimental effects its termination could have.

We are often told that an ounce of prevention is worth a pound of cure. This program is a clear example of an ounce of prevention. Is the administration committed to providing a for-credit academic experience to undergraduate students to tutor disadvantaged youth and adults?

COLLEGE CREDIT FOR COMMUNITY SERVICE PROJECTS

Answer. The administration is committed to increasing the involvement of college students in community service. However, it does not favor supporting programs that are designed exclusively to provide academic credit for tutoring activities. Narrowing the scope of student volunteer programs to one approach unnecessarily inhibits institutions' flexibility to develop innovative means of encouraging volunteer activity and needlessly limits the means by which students can serve their communities.

Question. How will it do so?

Answer. The administration is not unequivocally opposed to providing students with academic credit in return for tutoring, as long as this type of activity is included as an option within a community service program. Innovative Projects for Community Service can award academic credit as part of a community service activity, as long as credit is given in accordance with established institutional policies and is closely linked to or a part of regular academic work. The Learn and Serve America-Higher Education, which is administered by the Corporation for National and Community Service, also includes an option for providing academic credit for service activities. The amount of credit provided varies depending upon the policies of the participating institutions.

STUDENT LITERACY AND MENTORING PROJECTS ELIGIBLE UNDER INNOVATIVE PROJECTS FOR COMMUNITY SERVICE

Question. Will colleges and universities who are currently receiving funding under this program be allowed to continue their efforts under the Innovative Projects for Community Service?

Answer. Institutions that previously received a grant under the Student Literacy and Mentoring Corps (SLMC) program would be eligible to compete for funds under the Innovative Projects for Community Service program. Successful applicants could continue their current activities or support different innovative activities as outlined in their application. The administration has requested a \$1 million increase for Innovative Projects in fiscal year 1995.

Question. Will they receive priority consideration for funding of projects which are in the middle of their year grant awards?

Answer. Institutions that had previously received a SLMC grant would not receive special consideration under the Innovative Projects competition. Each application under the Innovative Projects competition would be considered on the basis of its own merits. Funding decisions would then be made based on the relative merits of the individual applications.

CORRECTIVE ACTION PROVISION IN PROPOSED ESEA LEGISLATION

Question. The Washington School Director's Association is concerned with the Corrective Action provision in the ESEA. This provision would take Federal funds away from schools if they do not meet the established requirement. Their concern is due to the fact that within this provision there are no exceptions or extenuating circumstances for schools receiving Federal funds. Is it possible to include language that would exempt schools from losing Federal funds if there are extenuating circumstances?

Answer. There is no requirement in the administration's bill that funds be withheld from schools for any reason. Under proposed Title I provisions, all LEAs would be required to take corrective actions against schools after three consecutive years of failure. The bill gives LEAs the flexibility to determine which actions would be exercised, and requires that LEAs take corrective actions listed in LEA plans. Withholding funds is among the options listed in the bill, which also include, but are not limited to: decreasing decisionmaking authority at the school level, making alternative governance arrangements such as the creation of a charter school, reconstituting the school staff, withholding funds, and authorizing students to transfer to other schools in the LEA.

The House bill eliminates the option of withholding funds from the list of corrective actions.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER BOND

PARENTAL INVOLVEMENT-PARENTS AS TEACHERS PROGRAM

Question. Earlier this week, conferees to the Goals 2000 bill agreed to include the Parents as Teachers program as part of a new title to the Goals bill which encourages parental involvement in the education of their children. My colleagues on this subcommittee will hear a lot about the Parents as Teachers program in the coming months, assuming that the conference report passes both Houses and we have an opportunity to seek appropriations for it. For those of you who are not familiar with parents as teachers, it is an early childhood/parent education program which provides parents with the information they need to be effective first teachers. I believe it is the premier school-readiness program in the country and eventually hope to see it adopted in every single school district.

I know, Mr. Secretary, that you have spoken at length lately of the importance of parental involvement in their children's lives, and I commend you for that. I believe the only way to turn the corner on some of our social problems is to reassert the importance of family responsibility and of good parenting. Will you then look favorably on the new title of the Goals bill and will you assure that it receives the attention of your Department?

Answer. I agree strongly that the role of parents is critical to achieving high levels of achievement for all children. Although our 1995 request did not include funds specifically for this title of the bill, I hope the funds that we have

requested--not only under Goals 2000, but also under ESEA--will provide the means for States and localities to ensure the kind of strong parental assistance and involvement that you and I both believe is essential. As for the specific means of involving parents, there are a number of good models around the country, and I do believe that it is important for State and local agencies to have the flexibility to design their own strategies. I can assure you that we will look closely at the Parental Assistance title as we develop our 1996 budget.

IMPACT AID CONSTRUCTION--BRADLEYVILLE SCHOOL DISTRICT, SPRINGFIELD, MISSOURI

Question. I would also like to say a word about a couple of Impact Aid issues in my State, one which is currently before the Department of Education and the other which I would like for you to consider.

First, the Bradleyville School District near Springfield, Missouri, applied for school construction money after their school roof collapsed in December of 1992. Since that time, they have been having classes in trailers. In December of 1993, Bradleyville was notified that they were first in line for school construction funds and that funds had been reserved for their project. Can you tell me what the status of this project is now, and when can they expect construction to begin?

Answer. Bradleyville is seeking assistance to replace a school facility that was lost due to a structural deficiency that caused the gym roof to collapse. We have reserved funds under section 14(c) for the Bradleyville school construction project, and we are currently evaluating the school district's application, information from the insurance company settlement, and the engineering report to determine the exact size and scope of the project to be funded, the total cost, and the local contribution that will be provided. If the school district agrees with our findings, formal approval of the project could be accomplished within the next few weeks, and architectural work would begin soon thereafter.

IMPACT AID CONSTRUCTION--WINONA R-III SCHOOL DISTRICT, MISSOURI

Question. Second, we have a years-old problem in the Winona School District in southeast Missouri, which received school construction funds in 1986. Due to a variety of circumstances beyond their control, including a statewide reassessment that caused their tax burden to more than double, they have been unable to come up with the "local effort" required under the law and are now saddled with a \$598,000 private debt. Despite repeated attempts in the last two administrations we were unable to get this problem resolved. I would simply like to ask for your commitment to have the appropriate members of your Department meet with members of my staff and with officials of the school district in an effort to put this problem behind us and get on with educating the kids in Winona.

Answer. Let me briefly describe the history of this problem. The Winona R-III School District, Missouri, applied for school construction assistance under section 14(c) of P.L. 81-815 in 1985. Under the provisions of the statute and implementing regulations, Winona was required to make a local contribution

toward the costs of the construction project. The regulations specified that an amount representing an LEA's unused bonding capacity, up to 12 percent of its assessed valuation, would be considered as an available financial resource.

In applying this requirement, the Department determined that the school district had no outstanding bonded debt and that Winona could raise approximately \$600,000 through its unused bonding capacity. The school district was unwilling to propose a local bond issue to the voters, but the superintendent and the school district agreed to make the required local contribution to fulfill the requirement, and the district accepted the grant award in 1987. At the time, the original project estimates set the local contribution at \$590,885 and the Federal contribution at \$600,000.

Since then, the local effort has remained the same but the cost of the project increased and the Department has now contributed approximately \$1.875 million for the project. Nevertheless, the district has repeatedly tried to have the local contribution amount to which it agreed reduced to \$200,000 or waived.

My staff has made every effort to provide assistance to Winona, consistent with the applicable legal requirements and the Department's treatment of other applicant school districts. We have informed the school district on numerous occasions that, without legislative action by Congress, we do not have the authority to waive or overlook the requirements of the program. Several times since 1987, the Congress has issued report language relating to this issue but has not provided any legislative relief. Report language does not carry the force of law and cannot overturn a statute or authorize waiving a regulation. We would certainly be willing to meet with your staff and officials from Winona to discuss this matter, but we are unable to offer any other solution.

OFFICE OF ELEMENTARY AND SECONDARY EDUCATION

STATEMENT OF THOMAS W. PAYZANT, ASSISTANT SECRETARY FOR
ELEMENTARY AND SECONDARY EDUCATION

ACCOMPANIED BY:

AUGUSTA SOUZA KAPPNER, ASSISTANT SECRETARY FOR VOCATIONAL AND ADULT EDUCATION

DAVID A. LONGANECKER, ASSISTANT SECRETARY FOR POST-SECONDARY EDUCATION

INTRODUCTION OF WITNESSES

Senator HARKIN. The subcommittee will resume its sitting.

I want to welcome the second panel, Dr. Thomas Payzant, the Assistant Secretary for Elementary and Secondary Education; Augusta Kappner, Assistant Secretary for Vocational and Adult Education; and David Longanecker, Assistant Secretary for Postsecondary Education.

Again, for the sake of time, we will include your statements in their entirety in the record. If you could briefly summarize your prepared testimony I would appreciate it very much. I will not ask any questions, and if anybody shows up I will hold all questions until we get through the panel.

I would start first with Assistant Secretary Payzant.

SUMMARY STATEMENT OF ASSISTANT SECRETARY PAYZANT

Dr. PAYZANT. Thank you very much, Mr. Chairman. I will try to be very brief in the interest of time in summarizing the testimony that has been submitted for the record.

We are requesting a total of \$10 billion for the elementary and secondary education programs this year, an increase of \$917 million, or 10 percent, over the fiscal year 1994 appropriation. This request is based on our reauthorization proposal for the Elementary and Secondary Education Act. That proposal, along with the Goals 2000: Educate America Act, would really reshape the Federal investment in elementary and secondary education to ensure that all American children have the opportunity to attain the knowledge and skills they need to lead productive lives.

We tried to take a comprehensive approach to education reform based on challenging academic standards for all students. That approach is guided by several important themes: helping children in need to achieve the challenging standards; improving teaching and learning with an emphasis on professional development for the teachers and other educators who work with those children day in and day out; ensuring that there is a safe and drug-free environment in which learning can take place; and promoting equity in educational opportunity.

We are also proposing increased flexibility in return for acceptance of responsibility for results at the local school district and school level. We know that the schools cannot do it alone; that we have got to expand linkages among parents, schools, and communities. We believe that it is important to target resources to where the needs are greatest.

TITLE I PROPOSALS

In the area of title I, we are recommending \$7.6 billion, which is a \$667 million increase over the 1994 level. This reflects the administration's resolution to invest substantial additional funding in title I if the programs are reworked to emphasize attainment to high academic standards.

PROFESSIONAL DEVELOPMENT PROPOSALS

We have a strong commitment to professional development in title II. We are requesting \$752 million for the proposed Eisenhower Professional Development State Grant Program. We do not just want to provide more money, but to focus on a different kind of professional development, which is no longer the one-shot, in-service program for teachers at 4 in the afternoon. We see a very thoughtful, sustained kind of professional development that really helps shape their instructional practices that help students meet the high standards.

The Secretary has mentioned our proposal on technical assistance. I will be happy to come back and answer questions on that.

SAFE AND DRUG-FREE SCHOOLS

In Safe and Drug-Free Schools, our request of \$660 million expands the Safe and Drug-Free Schools Program, and reflects our commitment to address the problems of violence, as well as drug abuse, in our schools and communities. This 40-percent increase in funding would support an improved program that would link schools and communities in the development and implementation of comprehensive prevention strategies.

EDUCATIONAL EQUITY

We are concerned about equity, as I noted. A number of program increases are recommended there, in the Women's Educational Equity Program, the Magnet School Assistance Program, and the Education for Homeless Children and Youth Program. We also are proposing new programs to deal with school finance equalization and a new Charter Schools Program.

IMPACT AID PROPOSALS

Under Impact Aid, one of our most important reauthorization proposals is a dramatic restructuring, which would simplify the program and distribute funds more equitably to those school districts that are genuinely burdened by Federal activities. Our proposal would eliminate payments for "b" children and redirect available funds to school districts that enroll "a" children.

PROGRAM ELIMINATIONS

In line with the efforts of the President in the National Performance Review, as mentioned by the Secretary, we are proposing the elimination of some programs which are duplicative of others, or would be more appropriately funded from other sources. In the elementary and secondary education area there are seven such programs: Law-Related Education, Dropout Prevention Demonstrations, General Assistance to the Virgin Islands, the Ellender Fellowships, Education for Native Hawaiians, Follow Through and Foreign Languages Assistance.

PREPARED STATEMENT

In conclusion, I want to emphasize that our reauthorization proposal and supporting budget recognize that reaching the national education goals requires strong support for State and local activities through a restructured Federal effort and the substantial infusion of well-targeted resources.

Mr. Chairman, thank you, and I will be happy to answer questions at the appropriate time.

Senator HARKIN. Dr. Payzant, thank you very much.

[The statement follows:]

STATEMENT OF THOMAS W. PAYZANT

Mr. Chairman and Members of the Committee, I appreciate the opportunity to appear before you to discuss the fiscal year 1995 budget request for Elementary and Secondary Education programs.

Our request is based on the Administration's Elementary and Secondary Education Act (ESEA) reauthorization proposal, the Improving America's Schools Act. This proposal, together with the Goals 2000: Educate America Act, would reshape the Federal investment in elementary and secondary education to ensure that all American children have the opportunity to attain the knowledge and skills they need to lead productive lives. It supports a comprehensive approach to education reform based on challenging academic standards for all students. This approach is guided by several important themes: helping children in need achieve to challenging standards; improving teaching and learning; providing a safe and drug-free environment in which to learn; and promoting equity in educational opportunity. We have also proposed increasing flexibility in return for accountability; expanding linkages among parents, schools, and communities; and targeting resources to where needs are greatest.

In support of our reauthorization proposal, our fiscal year 1995 budget request of \$10 billion would provide an increase of \$917 million, or 10 percent over the fiscal year 1994 appropriation, for elementary and secondary education programs. I will briefly discuss the highlights of our request.

TITLE I: HELPING CHILDREN IN NEED MEET HIGH STANDARDS

Federal programs, especially the current Chapter 1 program, which provides compensatory education to about 6 million children in almost all school districts across the country, tend to reflect and reinforce low expectations for poor, low-achieving children by emphasizing achievement in low-level basic skills. Yet research and the experiences of other countries have shown that all children can benefit from a challenging, enriched curriculum. In addition, many recent reports on the Chapter 1 program agree that low expectations also isolate the program from wider State and local reforms that could help close the gap between low-achieving poor children and their peers.

To address these and other fundamental problems with the way the current program operates, the Administration's reauthorization proposal would shift the program, which would revert to its original name of Title I, from providing remedial instruction to an entirely new objective of ensuring that poor children learn to challenging State standards established for all children. Under the proposal, States would integrate Title I into an overall strategy to achieve State and community re-

forms stressing high standards. Teaching and learning, curriculum, and assessments would all focus on this objective.

Our 1995 request for all Title I programs totals \$7.6 billion, and puts major new resources behind this restructuring proposal. The \$667 million increase over the 1994 level reflects the Administration's resolution to invest substantial additional funding in Title I if the programs are reworked to emphasize attainment to high academic standards, to provide new operating flexibility to schools in return for a commitment to improving student performance, and to target more of the funds to schools and communities with the greatest needs.

The request includes a 10.5 percent increase, to \$7 billion, for Title I Grants to Local Educational Agencies. Under the reauthorization proposal, funding for LEA grants would be split evenly between Basic and Concentration Grants. By allocating a greater share through Concentration Grants and making other formula changes, the proposal would ensure that the neediest schools get the assistance they need for reforms that will help poor children reach their full potential. When formula changes are fully implemented, the poorest quartile of districts and counties will receive approximately 50 percent of program funds, instead of 43 percent under current law.

Schools alone cannot ensure that poor children achieve challenging standards. Reaching high standards will require more support from parents and better coordination between Title I and other resources. Toward these ends, the request includes a \$26.6 million increase, to \$118 million, for the Even Start program. Even Start is an important component of the Administration's response to the national school readiness goal. By helping disadvantaged parents, as well as their preschool-age children, bolster educational skills, the program demonstrates an integrated model of family literacy that promises to help children learn to challenging standards once they enter school. In addition, the request includes increases for a restructured Migrant Education program and for the Neglected and Delinquent program to ensure that the hard-to-serve migratory children and institutionalized youth can benefit from improvements in Title I and in education generally.

TITLE II: IMPROVING TEACHING AND LEARNING

Real reform and improvement in elementary and secondary education requires a teaching force that is up to date in the content areas and skilled in imparting knowledge to diverse populations of students. Only intensive, ongoing professional development will ensure that educators have the ability to prepare their students to meet challenging standards. Therefore, we are requesting \$752 million for the proposed Eisenhower Professional Development State Grant program. This new program, which would replace Chapter 2 State and local programs and Eisenhower Mathematics and Science State Grants, would support intensive professional development in the core academic subjects within the context of State and local systemic reform efforts. The 1995 request, an increase of \$131.5 million or 21 percent over the combined fiscal year 1994 appropriations for the two antecedent programs, would make a significant contribution to increasing the number of well-prepared teachers, including those from underrepresented groups. An additional \$48 million, for a combined total of \$800 million for professional development, is requested to support model professional development programs and national activities under the Office of Educational Research and Improvement.

So that States and local districts can receive the kind of comprehensive technical assistance they need for undertaking systemic reform, we are proposing to consolidate 48 categorical assistance centers as well as the National Diffusion Network into 10 comprehensive regional technical assistance centers. Our budget request of \$70 million for the proposed Technical Assistance for Improving ESEA Programs would provide help to States and school districts in administering and implementing Federal programs authorized under ESEA, and disseminating proven and promising practices.

TITLE IV: FOSTERING SAFE AND DRUG-FREE SCHOOLS AND COMMUNITIES

An environment that is safe and free of drugs and violence is a prerequisite for successful schools. Our request for 1995 reflects the Administration's commitment to addressing the problems of violence and drug abuse in our schools and communities. We propose an appropriation of \$660 million for an expanded Safe and Drug-Free Schools Program, an increase of \$188.4 million or 40 percent over funds appropriated in fiscal year 1994. Taking an integrated approach to drug and violence prevention, our new program would link schools and communities in the development and implementation of comprehensive prevention strategies. It would target re-

sources to high-need schools and communities and tie State and local efforts to measurable goals and activities.

OTHER MAJOR INITIATIVES

The Administration's reauthorization proposal supports a variety of other programs that are designed to promote equity in educational opportunity, enhance flexibility, and improve educational achievement. For example, we are requesting:

- \$8 million for a new School Finance Equalization Assistance program, which would undertake research in and provide technical assistance on the equalization of local school funding.
- an increase of \$3 million, 152 percent, over fiscal year 1994 for Women's Educational Equity. Although women and girls have made substantial educational gains since the enactment of Title IX of the Education Amendments of 1972, research shows that significant gender inequities still exist in teaching and learning practices.
- an increase of \$12 million for the Magnet Schools Assistance program. Our reauthorization proposal would: encourage programs that benefit all types of children, not just an academic elite; promote the development of new magnet schools and innovative approaches; and build local capacity to continue projects after Federal funding ceases.
- \$15 million for a new Charter Schools program, which would offer increased flexibility in return for greater accountability. Charter schools, designed by teachers, parents, and other members of local communities, would be exempt from certain Federal, State, and local regulations and would focus on achieving ambitious educational goals tied to challenging State standards.
- \$30 million for the Education for Homeless Children and Youth program, a \$4.5 million increase over the fiscal year 1994 appropriation. This responds to the President's recent Executive Order on ending the cycle of homelessness and would give States and localities additional resources to meet the needs of this at-risk population.

REFORM AND SIMPLIFICATION OF THE IMPACT AID PROGRAM

One of the most important of our ESEA reauthorization proposals is the dramatic restructuring of the Impact Aid program to simplify the program and to distribute funds more equitably to those school districts that are genuinely burdened by Federal activities. Our proposed formula would consider the real cost of education in each State as well as the share of those costs that are provided from local resources. Our proposal would eliminate payments for "b" children and redirect available funds to school districts that enroll "a" children. The families of "b" children live or work in the local community, and contribute to the local tax base; therefore, these students present little burden to their school districts. Because of these proposed changes, our \$750 million request for the reauthorized program, while a reduction from fiscal year 1994, would actually increase payments to many school districts that enroll "a" children.

In conclusion, I want to emphasize that our reauthorization proposal and supporting budget recognize that reaching the National Education Goals requires strong support for State and local activities through a restructured Federal effort and a substantial infusion of well-targeted resources.

Mr. Chairman, my colleagues and I would be happy to answer any questions you may have.

BIOGRAPHICAL SKETCH OF THOMAS W. PAYZANT

Position: Assistant Secretary for Elementary and Secondary Education.

Education: Bachelor's Degree in American History and Literature, Williams College, 1962; Masters Degree in Teaching, Harvard University, 1963; and Doctorate in Education, Harvard University, 1968.

EXPERIENCE

1993—present: Assistant Secretary for Elementary and Secondary Education, Washington, D.C.

1982—93: Superintendent, San Diego City Schools, San Diego, California.

1978—82: Superintendent, Oklahoma City Schools, Oklahoma City, Oklahoma.

1973—78: Superintendent, Eugene Public Schools, Eugene, Oregon.

1969-73: Superintendent, Springfield Township, Montgomery County, Pennsylvania.

1967-69: Administrative Assistant to the Superintendent, New Orleans Public Schools, New Orleans, Louisiana.

1963-65: Junior high school history and special education teacher, Tacoma, Washington.

1962-63: High school history teacher, Belmont, Massachusetts.

Honors and awards: "The Executive 100"—Listed as one of 100 of the best school administrators in North America by the Executive Educator, February 1992; Harold W. McGraw, Jr., Prize in Education, December 1992; and Honorary Degree, Williams College, 1984.

Outside activity: Past Chair, Board of Directors, Council for Basic Education; Past Vice Chair, Board of Trustees, The College Board; and Past Member, National Board for Professional Teaching Standards.

STATEMENT OF AUGUSTA KAPPNER

Senator HARKIN. Next, we will turn to Dr. Augusta Kappner, Assistant Secretary for Vocational and Adult Education.

Dr. KAPPNER. Thank you, Mr. Chairman.

It is a pleasure to appear here and to talk about the 1995 budget request for school-to-work opportunities.

School-to-work opportunities, as you know, is the product of a partnership between the Department of Education and the Department of Labor to establish a national framework within which all States can create statewide school-to-work opportunity systems. These systems will be designed to help our young people acquire the skills, knowledge, abilities, and labor market information that they need to make a smooth and effective transition from school to career-oriented work, and further education and training.

The school-to-work initiative is designed to be nationwide in scope, and States will be coming on line as they are ready. By 1998, we expect that all States would have received 5-year grants with which to implement their statewide systems.

The initiative is currently proceeding on two funding tracks. During fiscal year 1994, funds were appropriated under the current legislative authority in the Job Training Partnership Act and the Carl D. Perkins Vocational and Applied Technology Education Act. For fiscal years 1995 and beyond, the program would run under the authority of the pending School-to-Work Opportunities Act, which we hope will be enacted very shortly.

The program will be closely coordinated with other Department of Education and Department of Labor programs, particularly the Goals 2000: Educate America Act, under which States and localities will be conducting their major comprehensive reform of their education systems.

For 1995, the first year of implementation under the new legislative authority, but the second year of the program, the Department of Education is requesting \$150 million for school-to-work opportunities. With the additional \$150 million requested by the Department of Labor, the program would be funded at \$300 million in 1995, an increase of \$200 million over total funding received in 1994.

Following an orientation conference in September 1993, in which teams from all States participated, States were invited to apply for development grants to permit them to undertake efforts that will result in a comprehensive plan for statewide school-to-work oppor-

tunities. These development grants have now been announced for all 50 States, the District of Columbia, and Puerto Rico.

States will use their comprehensive plans as the basis of competitive applications for larger implementation grants, the majority of which will be awarded in fiscal years 1995 and beyond. However, because some States are quite far along in the process of designing school-to-work opportunities systems, we are holding the first competition this spring with fiscal year 1994 funds. We expect that this competition will result in the award of four to eight implementation grants to States.

In addition to this State competition, we have also announced the first competition of local partnership grants, and will soon announce a competition for grants to high-poverty areas. As you can tell, work is well underway on the school-to-work opportunities initiative. The increase that we are requesting for 1995 would allow both Departments to award implementation grants to the next and much larger cohort of States, and to continue State and local implementation efforts begun in 1994.

In addition, the requested amount would allow us to do full-scale implementation of technical assistance, peer review, and the research and evaluation activities that will be authorized in the legislation.

PREPARED STATEMENT

This concludes my remarks on the 1995 budget for school-to-work, and I would be happy to respond to any questions on this and other topics.

Thank you.

Senator HARKIN. Dr. Kappner, thank you very much for your statement.

[The statement follows:]

STATEMENT OF AUGUSTA SOUZA KAPPNER

Mr. Chairman and Members of the Committee, it is a pleasure to appear before you today to discuss the fiscal year 1995 budget request for the School-to-Work Opportunities Act.

School-to-Work Opportunities is the product of a partnership formed by the Departments of Education and Labor to establish a national framework within which all States can create statewide school-to-work opportunities systems. These systems will be designed to help youth acquire the knowledge, skills, abilities, and labor market information they need to make a smooth and effective transition from school to career-oriented work and to further education and training.

The School-to-Work initiative is designed to be nationwide in scope. States will be "coming on line" as they are ready and, by 1998, we expect that all States will have received 5-year grants with which to implement their statewide systems.

The initiative is proceeding on two funding tracks. During fiscal year 1994, funds were appropriated under current legislative authority in the Job Training Partnership Act and the Carl D. Perkins Vocational and Applied Technology Education Act. For fiscal years 1995 and beyond, the program will be run under the authority of the pending School-to-Work Opportunities Act, which we hope will be enacted by the end of the month. The program will be closely coordinated with other Department of Education and Department of Labor programs, particularly the Goals 2000: Educate America Act, under which States and localities will be conducting comprehensive reform of their education systems.

For 1995, the first year of implementation under the new legislative authority, but the second year of the program, the Department of Education is requesting \$150 million for School-to-Work Opportunities. With the additional \$150 million requested by the Department of Labor, the program would be funded at \$300 million in 1995, an increase of \$200 million over total funding received in 1994.

Following a conference in September 1993, in which teams from all States participated, States were invited to apply for "development grants" to permit them to undertake efforts that will result in a comprehensive plan for a statewide school-to-work opportunities system. These development grants have now been announced for all 50 States, D.C., and Puerto Rico.

States will use their comprehensive plans as the basis of competitive applications for "implementation grants," the majority of which will be awarded in fiscal years 1995 and beyond. However, because some States are well along in the process of designing their school-to-work systems, we are holding the first competition this spring with fiscal year 1994 funds. We expect that this competition will result in the award of four to eight implementation grants. In addition to the State competition, we have also announced the first competition for local partnership grants and will soon announce a competition for grants to high-poverty areas.

As you can tell, work is well underway on the School-to-Work Opportunities initiative. The increase requested for 1995 would allow the Departments to award implementation grants to the next (and much larger) cohort of States and to continue State and local implementation efforts begun in 1994. In addition, the requested amount would allow full-scale implementation of the technical assistance, peer review, research, and evaluation authorities.

This concludes my remarks on the fiscal year 1995 budget request for the School-to-Work Opportunities initiative. I will be happy to respond to any questions you may have.

BIOGRAPHICAL SKETCH OF AUGUSTA SOUZA KAPPNER

Position: Assistant Secretary for Vocational and Adult Education.

Birthplace: New York, New York.

Education: Barnard College, A.B.; Hunter College, M.S.W.; and Columbia University, D.S.W.

EXPERIENCE

1993 to present: Assistant Secretary for Vocational and Adult Education, U.S. Department of Education.

1992-93: Acting President, The City College of New York.

1986-92: President, Borough of Manhattan Community College.

1985-86: University Dean for Academic Affairs: Instructional Research, Adult Learning and Developmental Education, The City University of New York.

1984-85: University Dean for Academic Affairs: Adult and Continuing Education, The City University of New York.

1978-84: Professor and Dean of Adult and Continuing Education, LaGuardia Community College.

1974-78: Associate Professor and Chairperson, Human Services Division, LaGuardia Community College.

1968-74: Held various teaching and administrative positions at Hunter College, New York City Community College, Columbia University School of Social Work and SUNY at Stonybrook.

Honors and awards: American Association of Women in Community and Junior Colleges Presidential Award (1989); Barnard College Medal of Distinction (1988); Columbia University Medal of Excellence (1988); Hunter College Hall of Fame (1987); and Hunter College School of Social Work Distinguished Alumni Award (1987).

STATEMENT OF DAVID A. LONGANECKER

Senator HARKIN. And now we will turn to Dr. Longanecker.

Dr. LONGANECKER. Thank you very much for the opportunity to be before you today.

I have a very unique and wonderful opportunity. Drs. Kappner and Payzant had the opportunity to share with you some wonderful things we are going to do in the future; I have the opportunity to share with you the good news of what we are implementing today, the Direct Student Loan Program.

This is a program that, in its first year, will provide 5 percent of the total Federal student loan volume in the country. That ac-

counts for 105 of the schools. We actually had about 1,100 schools apply for the first year, a phenomenal amount of enthusiasm for this program. We were only able to accept 105 because of the statutory limits on the program.

I will be very brief. Things are going about as well as one could imagine. It has been an extremely pleasant experience for those of us in the Department, and I believe for those who are participating with us in the first year of implementation of this program.

We have tried very hard to live up to the expectations that we gave to you last year. You and your colleagues provided us with the resources, both financial and staff-wise, to do this program. And we are dedicated to assuring that we manage the program over the next 7 years in a way that will make you proud of what you helped us accomplish last year.

We are being guided by six general principles, which are important to us. One is that this program will be focused on our customers. In this case our principle customers are the borrowers—the students and parents who borrow through our programs, then, secondarily, the institutions with whom we must work.

We want to make sure that this is a simple, straightforward program that people can understand and feel comfortable with. We want a program that will be simple and where all of the policies, systems, and procedures will ensure the highest levels of program integrity—something that has not always characterized Federal higher education programs, but that we are committed to providing in this program.

We want to use the best technology available so we have the model program for the 21st century. This program will be integrated into the existing structure of the student financial aid programs. It will not be a fiefdom unto its own. It is going to be an integral part of the programs within the Department and at the institutional level.

And we want to make sure that we deliver on time. At this point, we have delivered everything on time, or, in some cases, ahead of time. The 105 institutions that are working with us are quite excited about what we are doing. We are as well. We have pulled together a wonderful team. It is headed by Deputy Assistant Secretary Leo Kornfeld, who was a Deputy Commissioner of Education under Joe Califano. He has come to work with us after having run a couple of computer software companies and worked for a higher education institution. He has a remarkable background to help us in this area.

In addition to that, we have amassed a task force to help us in this regard that is second to none in the Department. We are also using a great deal of involvement from the higher education community as we bring this on. We are quite excited about it. We are quite pleased with what is going on.

Direct lending is a very high priority in the Department of Education. We are looking very much toward moving from 5 percent to 40 percent of overall loan volume in 1995–96. That is quite a reach. We are in the process right now of inviting institutions to apply, and selecting those for the second year.

I would tell you just as an aside that, as important as this program is to us, we are absolutely committed to assuring that every

student has access to a student loan, whether they are in the Direct Student Loan Program or the existing FFEL program, the Federal family education loans, and that we will assure, to the extent that we can, that that access is not interrupted for any students.

PREPARED STATEMENT

With that, I will end my remarks, and I thank you for the opportunity to appear before you today. I will be happy to respond to any questions that you might have.

[The statement follows:]

STATEMENT OF DAVID A. LONGANECKER

Mr. Chairman and Members of the Committee, thank you for this opportunity to discuss the Department's implementation of the Federal Direct Student Loan Program. In academic year 1994-95, the Direct Loan program will lend an estimated \$900 million to 270,000 students, accounting for 5 percent of the student loan volume. The program will expand greatly in academic year 1995-96 when an estimated \$8.3 billion, or 40 percent of the student loan volume, will be loaned to 2.3 million students. Under this new program, loan capital is provided directly by the Federal Government, using Treasury borrowing, rather than through costly Federal subsidy of private lenders and guaranty agencies. The program will make it easier for student and parent borrowers to obtain, and, by offering a variety of repayment options, repay education loans. I am pleased to report that implementation of this important new program is proceeding extremely well and on schedule.

The implementation of direct lending offers a unique opportunity to "reinvent" government. Before detailing the specific steps we have taken, I would like to give you the six principles that have guided our implementation efforts. These guiding principles are that: all policies, systems, and procedures will lead to the highest level of program integrity; the program will be simple to understand and administer for both students and schools; the best available technology will be employed to achieve efficient and cost-effective delivery; the program will be integrated into the existing structure of the student financial aid programs, both in the Department and at the institutional level; the best quality service will be provided to all of our "customers"—students and parents, schools, and taxpayers; and the program will be implemented on time.

I will briefly discuss the steps we have taken to ensure timely, logical, and cost-effective implementation of the Direct Student Loan Program.

STAFFING AND RESOURCES

The implementation of the Direct Loan program is a very high priority for the Department. To ensure that the program is successfully implemented, we have brought aboard Leo Kornfeld as Deputy Assistant Secretary for Student Financial Assistance Programs. Leo brings vast management experience including prior experience in the Department and at the institutional level. The Department appointed a Direct Loan Task Force composed of experienced and highly qualified personnel who are specialists in program management, systems, policy, accounting, financial management, budget, policy analysis, contracts and training. The Task Force is responsible for coordinating and managing program implementation activities; however, implementation has been fully integrated into the overall organization of the student financial assistance programs. Within this structure, additional personnel and other resources have been allocated to implement the Direct Loan program.

Part of our commitment to this program is to see that it is provided adequate resources to succeed. The Department has an approved hiring plan through fiscal year 1995 and has received a waiver from Executive Orders requiring employee reductions that will permit us to hire up to 220 full-time equivalent (FTE) employees to implement Direct Loans and manage the transition from the Federal Family Education Loan program (FFELP) in 1994. In fiscal year 1995, the number of FTE will increase to 350. Eventually, we estimate that 520 FTE will be assigned to Direct Loan program implementation and FFELP transition activities.

REGULATIONS GOVERNING DIRECT LOANS

Establishing the rules and regulations to govern a new program is an essential first step in successful program implementation. In the case of the Direct Loan program, the development of two sets of rules has been occurring concurrently.

The first set of rules will be used for the academic year 1994-95 only. These rules have been developed without going through the usual rulemaking process. Last September, the Department published a notice in the Federal Register describing the school selection criteria and application procedures for the Federal Direct Student Loan Program for academic year 1994-95. We received more than 1,100 applications. Of these, 900 were from institutions eligible to participate in the Direct Loan program. Because the law restricts Direct Loans to 5 percent of new student loan volume in 1994-95, the Department selected fewer schools than were eligible. Last November, six weeks ahead of schedule, the Department notified 105 institutions of their selection to participate in the initial year of the program. The Department has also published final regulations establishing the administrative requirements and program procedures for schools participating in the Direct Loan program in the first year. We anticipate publishing another notice describing the loan repayment provisions for loans made during the first year prior to July 1. This will be the last notice issued under the Direct Loan program that is not subject to negotiated rulemaking.

While we have not gone through the normal rulemaking process, I would like to emphasize the importance we have placed on public participation in all our development efforts. We meet monthly with representatives of the postsecondary education community to discuss issues related to Direct Loans. The purpose of these meetings is to solicit comments, ideas, concerns, and suggestions on all aspects of Direct Loans. In addition, we held an orientation conference with all of the institutions participating in the first year to seek their counsel on what we are doing and how we are doing it. Finally, we have installed a Direct Loan bulletin board on the Internet system that encourages and facilitates communications between schools and the Department.

For future years, we are developing regulations to govern all aspects of the Direct Loan program—institutional selection, administrative requirements, and terms of repayment, including income contingent repayment—through the negotiated rulemaking process. We have established an advisory committee to advise us on the standards, criteria, procedures, and regulations governing the Direct Student Loan Program, including the repayment provisions, which become effective in academic year 1995-96. We have met with the advisory committee twice, and meetings will continue until June, when we expect to have a Notice of Proposed Rulemaking ready for publication in the Federal Register.

We have already published a notice in the Federal Register describing the school selection criteria and application procedures for the program for academic year 1995-96, during which the program will grow from 5 to 40 percent of total student loan volume. Eligible institutions that submitted applications for 1994-95 but were not selected will not have to re-apply. They will be automatically selected if still eligible, and will be so notified by June 15, 1994. For other schools interested in participating, we will employ a rolling application and selection process. We have emphasized to schools interested in participating in the Direct Loan program in 1995-1996 that they should apply early, since we will stop selecting schools as soon as the new loan volume of selected schools comprises 40 percent of the total projected volume.

DESIGNING A SYSTEM TO ENSURE EFFICIENT DELIVERY AND SERVICING OF DIRECT LOANS

In order to assure that the Direct Loan program is operational on July 1, the Department has had to work quickly to modify existing systems and build new systems to originate loans, deliver funds, reconcile accounts, and service loans. As I previously mentioned, our goals have been to simplify the administration of the program and to integrate it into the existing structure of the student financial aid programs. To this end, the Department developed software to support schools' administration of the Direct Loan program. This software includes an optional financial aid packaging module, as well as loan origination, fund draw down, reconciliation, and student status confirmation report modules. These Direct Loan modules are incorporated into the Department's EDEpress software and are available to schools free of charge. In developing the software, we were assisted by a group of practicing financial aid officers and institutional data processing experts.

The Department has awarded the Direct Loan servicing contract to Computer Data Systems, Inc. (CDSI), of Rockville, Maryland, and a team of five subcontractors. The contractors will maintain the Department's data base on Direct Loan re-

cipients; provide alternate origination services for schools that are unable to, or choose not to, originate loans; administer the flexible repayment options available to borrowers, including income contingent repayment; handle billings and collections; and provide customer service.

The Department also has modified its Payment Management System (PMS) and the National Student Loan Data System (NSLDS) to accommodate the Direct Loan program. The modified PMS will enable schools to draw down and account for Direct Loan funds to be disbursed to students; it will also interface directly with the Direct Loan software provided to institutions. The NSLDS is being modified to record borrower-specific data to be used for eligibility screening and for analysis activities that can further improve our management of the Direct Loan program.

The Departments of Education and Treasury have been meeting to evaluate the feasibility of various options for IRS involvement in loan servicing and collection. Jointly we convened focus groups to obtain the views of students, borrowers, and the financial aid community about IRS involvement in student loans. We are preparing a report to Congress, currently scheduled for delivery in June, that will describe various approaches under consideration by the Administration. We will provide an implementation plan for IRS involvement in student loan collections, if such participation is deemed feasible and desirable. The IRS will share income information with the Department and continue to offset tax refunds for borrowers currently in default under the student loan programs.

TRAINING AND CUSTOMER SERVICE

The Department has developed and implemented a comprehensive plan for providing training to all schools participating in the Direct Loan program, with a focus on Direct Loan policies and procedures and hands-on use of the software described earlier. Training for first-year participants began in January, and 20 sessions are scheduled through mid-April. Schools scheduled to participate in 1995-1996 will begin training this summer so that they will have adequate time to implement the program on their campuses.

The Department has established a customer service unit to respond to inquiries and resolve problems encountered by any participant in the student assistance programs. This unit will staff a toll-free hotline and administer the Direct Loan bulletin board on the Internet to track inquiries and responses to ensure timely and accurate information dissemination.

The Department's software development contractor will provide technical assistance to all participating schools. The contractor has a toll-free hotline for schools to use for help in setting up the software and in understanding technical specifications. We are prepared to provide on-site assistance to participating schools to help them install and operate the software as necessary. Also, we are encouraging and facilitating a "tail-gating" program through which one school would provide leadership and technical assistance to other schools in its area.

ACCOUNTING AND FINANCIAL MANAGEMENT SYSTEMS

The Department, working closely with the Office of Management and Budget (OMB), Department of Treasury, and the General Accounting Office, has been working to establish accounting and financial management requirements and systems. To date, we have negotiated an agreement with the Department of Treasury and OMB regarding the application of the requirements of the Credit Reform Act. In addition, we have documented fund flows from loan disbursement through loan repayment, and close-out, and we have identified the accounting and financial reporting systems associated with these fund flows.

The Department is designing systems to track the status and history of new and outstanding loans, record and track all cash flows associated with each cohort of loans, maintain all necessary fund controls, and maintain the data necessary to measure the accuracy of the loan subsidy estimates.

CONCLUSION

The implementation of the Federal Direct Student Loan Program will be fully integrated into the on-going operations of the Department. To be successful, the Office of Postsecondary Education, and the Department as a whole, must be a high-performance, results-oriented organization. We are committed to making it such. Successful implementation of Direct Loans will also require us to strengthen our oversight and institutional eligibility activities. The program integrity provisions in Part H of the Higher Education Act, added in the amendments of 1992, provide us with

important new tools to strengthen these efforts. The key to success, however, is our commitment to better management of the Federal student financial aid programs.

I am pleased with our work thus far in implementing the Federal Direct Student Loan Program and appreciate this opportunity to share our accomplishments with you. I will be pleased to respond to your questions.

BIOGRAPHICAL SKETCH OF DAVID A. LONGANECKER

Position: Assistant Secretary for Postsecondary Education.

Birthplace and date: Sterling, Illinois, March 23, 1946.

Education: Stanford University, Ed.D., The George Washington University, M.A., Washington State University, B.A.

EXPERIENCE

1993-present: Assistant Secretary for Postsecondary Education, U.S. Department of Education.

1988-93: Executive Director, Colorado Commission on Higher Education.

1984-88: Executive Director, Minnesota Higher Education Coordinating Board.

1981-84: Deputy Executive Director, Minnesota Higher Education Coordinating Board.

1980-81: Chief of the Education and Training Unit, Congressional Budget Office.

1977-80: Policy Analyst for Postsecondary Education, Congressional Budget Office.

1975-77: Assistant to the Vice President for Academic and University Affairs, Stanford University.

1972-74: Assistant Director of Housing, The George Washington University.

DIRECT LOANS AND PROGRAM INTEGRITY

Senator HARKIN. Dr. Longanecker, thank you very much.

I would just start with you, then. You were here, I am sure, listening to the questions propounded by Senator Cochran earlier that some schools are complaining about this, that in fact I think a statement was made that this may be costing more money than it is saving. How do you respond to the questions and the comments made by Senator Cochran? I am concerned about that also.

Dr. LONGANECKER. There really were two issues that Senator Cochran raised. One is the general concern in the higher education community with which we have been dealing over the last few months with respect to the regulations that we are developing for implementation of the higher education amendments of 1992. There is a great deal of concern in the community over those regulations, and we have been listening very closely.

We obviously have to implement the law, and we have to develop regulations that are consistent with that law. Yet, we also want to be sensitive to the concerns from the community.

These regulations will apply whether we have direct lending or any other set of programs. But because they are occurring and being implemented at the same time that we are implementing direct lending, there is some confusion within the community between the two.

The second issue is direct lending. There is an investment cost associated with direct lending as we bring up a new program. It is in the range of the amounts that Senator Cochran indicated.

We will, however, reap a substantial benefit from that initial investment over the first 5 years of this program. In combination with cost reductions achieved in the FFEL program, direct loans will achieve savings over the first 5 years of \$4.3 billion.

I have every reason to believe that we will achieve at least that level of savings. After the first 5 years, we will be achieving savings of over \$1 billion a year. It is well worth the initial investment for what we will eventually reap.

Senator HARKIN. So an initial outlay problem, but we will come back in a couple of years.

Dr. LONGANECKER. In a very substantial way.

ADULT LITERACY

Senator HARKIN. Dr. Kappner, the results of the National Adult Literacy Survey released last year suggest that as many as one-quarter of American adults—more than 40 million individuals—are functionally illiterate. I understand the budget includes a small increase for Adult Education State Grants, but is the Department developing any broader strategy to respond to the situation, or are we just going to continue to throw some nickles at it?

Dr. KAPPNER. The Department is planning to develop a broader strategy. As you noted, there is a small increase in the Adult Education Basic State Grants Program.

There is, however, also a 27-percent increase in the Workplace Literacy Partnerships Program, which brings education and business together to try to provide literacy training for those who are already in the workplace and which hopefully will lead to a greater investment on the part of the private sector in tackling the issue of literacy.

There is also a 29-percent increase in the Even Start Program, which is a literacy program that serves children and adults, usually their parents.

Additionally, we are working very closely with the States to increase the capacity of the State Literacy Resource Centers and with and through the National Institute for Literacy to increase the capacity locally to address this problem.

We are also involved in helping States strengthen staff development, which is essential to launching and doing better and more effective literacy programs, and improve the method of delivering services.

Through the National Evaluation of Adult Education programs, we will be looking at what works and disseminating more information on what works. We are approaching, as you know, the reauthorization of the Adult Education Act. Reauthorization will provide us the opportunity to take a broader approach and bring into play what we know about technology and the way in which technology could help us to deliver better adult education and literacy services to a much larger population in a much more effective way.

ADULT EDUCATION RESEARCH

Senator HARKIN. Are you confident that enough research has been done on how we can get to adults who are functionally illiterate to teach them in the most cost-effective manner? Have we experimented enough to know what kind of models work and what does not work?

Dr. KAPPNER. I think we know a good deal about what models work—often that entails bringing together in one place all of the

kinds of resources that adults need to make it possible for them to learn. I think there is always room for more experimentation to see if you can have good outcomes, and it is our responsibility to make sure that that kind of information is disseminated widely.

It is also clear that as we approach reauthorization, we need to be thinking of the ways in which adult education is provided by a variety of Federal resources, and seeing how we can bring the Adult Education Act together with some of the resources that might exist in other Federal authorities.

GENDER EQUITY IN EDUCATION

Senator HARKIN. Let me ask Dr. Payzant about the gender equity in education. Research shows that significant inequality still exists in teaching and learning practices. Your budget includes \$5 million, a 150-percent increase in funding for the Womens Educational Equity Program. While the percent increase is large, the total amount is not much.

How will these additional funds be used, and will statewide reform plans developed under Goals 2000 be required to include strategies for improving gender equity in education?

Dr. PAYZANT. Mr. Chairman, let me address the latter part of your question first. Goals 2000 speaks to all students in America, and the all is not a word to be taken lightly. That means young men, young women, boys, girls, students of different socioeconomic backgrounds, different races, and ethnicities. As a State, school district, and school put together their plans, they have to show that they are addressing and meeting the needs of all students.

In addition, there is a very strong policy statement included in our Elementary and Secondary Education Act reauthorization proposal that would require States and the LEA's to address issues of equity, and gender equity.

In recent years, there has been considerable discussion about improving professional opportunities for women in nontraditional fields, such as math and science. We encourage continued attention to these and other gender equity issues not only through the Women's Educational Equity Program, a small discretionary grant program, but through our broader initiatives as well.

In the Women's Educational Equity Program, the increase is big in terms of percentage but modest in terms of dollars. It would provide opportunities not only for the States but for local groups or local school districts to address a particular aspect of gender equity. Through grants, LEA's, and SEA's could demonstrate what might be effective in terms of a curriculum, teacher strategies, or ways in which a school district or schools might work to raise the consciousness of people so that they could be more effective in the classroom in working with students to bridge the gap that, all too often, is there.

SCHOOL-TO-WORK INITIATIVE

Senator HARKIN. At last year's hearing, Dr. Kappner, I expressed concern that it might be difficult to establish an equal partnership between the Departments of Labor and Education in administering the school-to-work initiative. The Labor Department's Employment

and Training Administration employs 1,600 staff, while the Education Department's Office of Vocational and Adult Education has a little over 100.

I just want to know how things have worked out. How is that relationship working out?

Dr. KAPPNER. The relationship is moving along quite well. It is really a collaboration that is absolutely breaking new ground in terms of two agencies working together to design a program and to find ways to implement that program.

We have a well-worn path across the mall that we have both treaded as we have worked together to bring the initiative as far as we have.

Since last summer, there have been, as you may know, several teams working across both agencies—teams that contain staff from both Education and Labor. We feel very good that by working together those teams have developed a product that is better than either of us could have produced alone.

Currently, as we await the passage of the legislation, we have an interim management council and a steering committee which is guiding the decisions on policy and planning for the future structure of implementation. It is our plan, as is required by the legislation, to develop a more permanent structure to which we will both be assigning some staff full-time—probably in equal numbers so that there will be a balance—so that we can continue the level of collaboration and success that we have established so far.

GIFTED AND TALENTED EDUCATION

Senator HARKIN. Well, I am glad to hear that.

Just a couple of other ones. Dr. Payzant, in all the talk about chapter 1, or title I reaching underserved children in terms of rehabilitation, Public Law 94-142 making sure that each child gets an equal and appropriate education, I have not heard anything yet today from anyone about another aspect of education that has been supported up here not only on this committee, I think, but I can say the entire Congress, and I am wondering if it is just being lost sight of, and that is the gifted and talented program.

What can you tell me about that? I do not hear it in Goals 2000, I do not hear it in any of the programs we are talking about, in any kind of a way of saying that, you know, we are going to have a determined effort to reach out to schools to find those children that are indeed gifted and talented, regardless of their economic status, and put them into specialized programs that are challenging for them. What is the status of gifted and talented? How come I do not hear anything from the Department about it?

Dr. PAYZANT. Mr. Chairman, we have not forgotten about that at all. Included in our ESEA reauthorization package is a proposal for the Javits Gifted and Talented Education Program. With respect to the budget, the appropriation that we are recommending is a modest increase over 1994 levels. We are at about the \$10 million level in that program.

The direction that we are proposing in the reauthorization is that we focus more on taking what we have learned from programs funded under Javits in the past that have been really successful in engaging students, getting them motivated, excited, and successful

with their learning. We will encourage those who submit applications for grants to show how they might expand on these strategies and use them to engage more students and to enable more students to benefit from them.

As a former superintendent, most recently, for the last 10 years in San Diego, CA, which has a very active gifted and talented program, we were very successful in providing opportunities for students that for years had been overlooked because people assumed that they might not be gifted and talented. We were able to bring more students who had been locked out of gifted and talented programs in. There definitely is a role for Federal support, but we must take into account what we have already learned about successful gifted and talented programs and make that available to more students.

Senator HARKIN. So it is a little over \$10 million, is that what it is?

Dr. PAYZANT. Yes.

Senator HARKIN. And you say you are addressing it in the Elementary and Secondary Education Act authorization which we are going to have up very shortly?

Dr. PAYZANT. Yes.

Senator HARKIN. Are you proposing changes?

Dr. PAYZANT. The major change in focus is that we would encourage those who are applying for grants to build on the success that has been found in previous experiences under the Javits Gifted and Talented Program, and to develop ways in which to expand the opportunities for students who are gifted and talented to be brought into the kinds of learning situations and classrooms with teachers who use approaches that really make a difference with kids.

There is another thing that is going on as a result of research, and that is to broaden our understanding about giftedness and how to define it and to not limit our thinking about giftedness to a very narrow focus on someone's linguistic ability or an ability that might be measured by a single test. We need to recognize that there are various kinds of giftedness and talent that can be nurtured in children and that that can be very important both as a motivator and providing kids with the opportunity to do well.

Senator HARKIN. Is there a better way than just a simple IQ test?

Dr. PAYZANT. Yes, indeed.

Senator HARKIN. How early do you think kids should be tested for gifted and talented programs?

Dr. PAYZANT. Not too early. If you look at how children develop in San Diego, we did not test children before the second or third grade because we felt very strongly that there is such a wide variation in the rate at which children develop in those early years of 5, 6, and 7 years of age, that to try and label their giftedness that early in many instances would be a disservice to the child.

Senator HARKIN. Well, I look forward—I want to take a look at that in the reauthorization and take a look at what you are doing on that, because I noticed its absence in any testimony and anything like that, and when I see that, I wonder if it is not being brushed aside, you see.

Dr. PAYZANT. That program is actually operated out of the Office of Educational Research and Improvement, so it would be part of their budget and not the Office of Elementary and Secondary Education, but I am familiar with it because it is part of the reauthorization on the Elementary and Secondary Education Act.

POSTSECONDARY PROGRAM INTEGRITY

Senator HARKIN. One last question. Dr. Longanecker, this came up earlier. I forget who raised the issue here, but it has to do with the new State Postsecondary Review Program—

Dr. LONGANECKER. Yes.

Senator HARKIN [continuing]. And the new standards for accreditation. A lot of concerns are being generated out among the higher education community. Believe me, I understand the need to protect taxpayers and the students also. I have had a lot of hearings highlighting this problem, going back several years, but I am hearing from what I consider to be very legitimate right-thinking upstanding schools in the State of Iowa that the requirements may go a bit too far, and they may be caught up in this sort net, even though they have not done anything wrong.

Institutions are worried about new data collection demands, Federal intrusion into decisions on program content and curricula, and the failure to take into account differing institutional missions in setting performance standards.

How are these issues going to be addressed during rulemaking, and would you tell me again—I thought I heard earlier when the rule was going to be out. Did I hear May?

Dr. LONGANECKER. May 1.

Senator HARKIN. May 1, and the hearing date is closed now, right?

Dr. LONGANECKER. That is correct.

Senator HARKIN. So you are in the process of promulgating that rule.

Dr. LONGANECKER. Right.

Senator HARKIN. I guess what the schools are telling me is, they want some kind of assurance that those schools that have no history of problems, that have been doing a good job, that they will not be burdened with all kinds of heavy new regulations and paperwork and things like that. That is what they are concerned about.

What kind of reassurance can you give them, if they have got a clean record, that they will not have to spend a lot more money on doing different things than what they have done in the past?

Dr. LONGANECKER. We have spent a great deal of time since putting out the draft regulations—in fact, before putting out the preliminary proposed regulations—working with the community to better understand their concerns and to share with them various ways in which we might implement these new program integrity provisions. We obviously have to implement the law and we have to be consistent with the law.

We have heard the same concerns from the community that you have mentioned. We want to work with them to allay their fears, and, as the Secretary indicated, we have had a series of hearings

around the country where we had the opportunity to talk with college presidents and get their advice.

We have received a great deal of comment on both the new State Postsecondary Review Program, regulations and the accreditation regulations. We also have a new executive order. Executive Order 12866, in which the President requires us to regulate as little as necessary. We must balance that mandate from the President, and the advice we have received from the community, with the need to assure integrity in Federal student aid programs. We believe we can find a balance with which many if not most in the community will be reasonably comfortable.

There will be some additional burdens because, prior to the higher education amendments of 1992, we did not have adequate oversight of the system of higher education. The States were not doing their job very well. I can say that fairly assuredly—I was a State official during the 12 years prior to coming here—that some of the blame rested on us in the States.

Certainly the accrediting associations had not done their job very well, and I think that without doubt the Department itself had not done its job well. The higher education amendments of 1992 made the responsibilities of the Federal and State governments and accreditors much more explicit, and that will put some additional burden on the community. It is our job to try to find a way to minimize that burden, and to assure that we are spending our precious resources looking at those institutions where there is the greatest Federal risk and the greatest risk to students, rather than focusing on those institutions that do a good job.

VOCATIONAL EDUCATION EQUIPMENT

Senator HARKIN. Thank you very much, Dr. Longanecker.

One last thing, Dr. Kappner, in vocational education, one of the things I hear about as I go around and visit vocational schools is the lack of adequate and up-to-date equipment, the tools that students need to work on and to learn in order to move from school to work, many of these are outdated, they are old, they are not state-of-the-art, and, therefore, they learn on certain pieces of equipment or learn a certain process, and that is no longer applicable out in the marketplace.

I do not know the parameters of this, and I think we have to get a handle on it. I have heard a lot about it as I go around, and I know we focus on the educational aspect and on teachers and the school-to-work transition, but a lot of this has to do with understanding processes, equipment, functions, things like that, of items that are outdated, and I am just wondering if you have looked into that. Is there any kind of research going into that, what might be needed or are these just isolated cases?

Dr. KAPPNER. No; I think I would agree with you that there is a need to take a look at how well or poorly equipped our vocational education institutions are across the United States. I think that is one area in which the school-to-work initiative will be helpful, though, because if a State or a community is successful in bringing together the workplace with schools in the way that we anticipate under this initiative, it will open up new resources to students in terms of equipment that they might have access to.

Just on Friday I was visiting a vocational education school in which they were doing metalworking. I visited their classroom, which they still call a shop, and looked at their equipment, and realized they could only go to a certain level using that equipment, but they were having the opportunity through their relationship with business, to practice and learn on much higher-quality equipment—the kind of equipment they might actually have in the workplace. We hope that that is one of the problems that the school-to-work initiative will help us to address.

Senator HARKIN. Very good. Well, I look forward to getting more information from you on this, because I think we have to get a handle on how big a problem it is, and what the Federal role ought to be in providing some of that equipment.

Thank you all very much. I appreciate your being here and being so patient, and thank you for your response to our questions.

Dr. KAPPNER. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ACADEMIC PERFORMANCE OF DISADVANTAGED CHILDREN

Question. The administration's proposal to modify the Chapter 1 funding formula is based in part on research showing that academic performance in a particular school is closely related to the overall rate of poverty among the students attending that school. Please provide a summary of this research, including a comparison of the performance of poor children attending low-poverty schools with that of poor children attending high-poverty schools.

Answer. Findings from major research studies provide substantial evidence that children in high-poverty schools are often the most at risk of academic failure.

The Longitudinal Study of Chapter 1 (Prospects) indicates that:

- One-third of the students in schools with very high concentrations of poverty fall in the bottom 20 percent on achievement, compared with only 8 percent of students in schools with the least poverty.
- The average achievement of all students in high-poverty schools is almost the same as the average for Chapter 1 students in low-poverty schools.
- Reading scores of 4th grade students receiving free or reduced-price meals drop as the poverty level of the school rises. The decline is quite abrupt beginning in schools that have 50 percent or more of students receiving free or reduced-priced meals.
- One third of the parents of children in high-poverty schools lack a high school diploma or General Educational Development (GED) certificate. By comparison, only 3 percent of the parents of children in low-poverty schools do not have at least a high school education.

In addition, data from the National Assessment of Educational Progress show that:

- The learning gap between students in disadvantaged and advantaged urban communities narrowed in the 1970s and 1980s, but has begun widening again. Eighth-grade students in disadvantaged urban communities were among the only ones not to register gains between 1990 and 1992 on the NAEP mathematics assessment.
- Of the 13-year-olds tested at reading level 250 (interrelating ideas and making generalizations), 73 percent of children living in advantaged urban communities showed proficiency, compared with 41 percent in disadvantaged urban communities.

- Of the 17-year-olds tested at the highest math level, 15 percent of students in advantaged urban areas showed proficiency, compared with 2 percent of those in disadvantaged urban communities.

Other recent studies and reports also contribute findings about how poverty influences student performance:

- In the poorest schools, half of all eighth-grade students scored in the lowest quartiles in reading and math, and four out of every five students scored below average (National Educational Longitudinal Study, 1990).
- High-poverty Chapter 1 schools are far more likely than low-poverty Chapter 1 schools to be identified, on the basis of student test scores, for Chapter 1 program improvement (The Chapter 1 Implementation Study, 1993).

IMPACT OF CHAPTER 1 FORMULA CHANGES ON RURAL AREAS

Question. In developing its proposal to change the Chapter 1 formula, did the Department consider options that would at least preserve the current level of resources available to poor rural schools while at the same time shifting more funding to high-poverty urban districts? If so, please describe these options.

Answer. Because the Department is concerned about improving education for the increasing number of poor children living in poor rural areas, its Chapter 1 formula proposal was designed to provide substantial funding increases to poor rural school systems as well as poor urban school systems. Rural counties are actually more likely than other counties to receive funding increases under the administration's proposal (because they are more likely to have high poverty rates): preliminary estimates show that 57 percent of rural counties would receive funding increases, compared to 52 percent of counties overall. For example:

- Rural East Carroll Parish in Louisiana, with a child poverty rate of 70 percent, would receive an estimated 25 percent increase in Title I funding in fiscal year 1995 and 33 percent when the formula change is fully phased in.
- In comparison, an urban area like Philadelphia, with a poverty rate of 30 percent, would receive a 20 percent increase in Title I funding in fiscal year 1995, eventually rising to a 28 percent increase.

The General Accounting Office (GAO) recently issued a report concluding that more rural counties than urban counties would lose funds due to the proposed eligibility changes; however, GAO looked only at eligibility changes affecting a small number of counties and did not examine the impact of the administration's full proposal on the distribution of funds. The report did not

mention, for example, that at the State level, the States that benefit the most under the administration's proposal are those GAO identified as having the highest levels of rural poverty. We estimate that the 10 States with rural poverty rates of 25 percent or more would receive an average increase of 15 percent -- 50 percent higher than the 10 percent total funding increase -- and the 3 States with the highest rural poverty rates (30 to 36 percent) would receive an average increase of 18 percent.

TEACHER PROFESSIONAL DEVELOPMENT

Question. Assistant Secretary Payzant, you're probably aware that the Education, Arts, and Humanities Authorizing Subcommittee is at this moment holding a hearing on teacher professional development in preparation for reauthorization of the ESEA. I'm sorry I had to miss that hearing, but I wonder if you might tell us how important you believe professional development efforts are for the success of education reform?

Answer. Teachers and administrators who can prepare their students to meet high standards are an integral part of educational reform activities. Yet the Nation faces a major need for expanded professional development activities. In a 1988 study, the Carnegie Foundation for the Advancement of Teaching found that 20 percent of teachers felt that they were teaching subjects that they were unqualified to teach. The National Center for Education Statistics notes that minorities are significantly underrepresented in the teaching force relative to the enrollment in schools: 29 percent of students in public schools, but only 13 percent of public school teachers, are minority. A 1988 study by the National Science Foundation reported that nearly one-half of the Nation's 2.2 million mathematics and science teachers, especially those at the elementary level, require extensive upgrading in both disciplinary competency and pedagogical skills.

To make a significant contribution to increasing the number of well-prepared teachers, including those from underrepresented groups, we have proposed the Eisenhower Professional Development program. This program would support high-quality, intensive professional development that is tied to comprehensive, systemic reform programs. These professional development activities would expand teachers' content knowledge and improve their instructional practices. The program could also fund supplementary efforts, such as professional networks, designed to institutionalize professional development in States and districts.

PROGRAM COORDINATION

Question. As an appropriator, I am concerned about how all the pieces of the administration's reform agenda fit together.

For example, I understand that Goals 2000, the new Title I program, and the new Eisenhower program all provide substantial support for teacher professional development. Can you tell me what steps the Department will take

to integrate these teacher training activities and avoid costly duplication of effort?

Answer. For Goals 2000, Title I, and the Eisenhower Professional Development program, States and local districts would be required to develop comprehensive reform plans. States and local districts would coordinate their Title I and Eisenhower plans with each other and with either the Goals 2000 plan or, if the State or district is not developing a Goals 2000 plan, with other ESEA plans. This requirement will help to ensure that all professional development activities complement each other and are part of the same overall strategy.

Additional provisions would also foster collaboration. For example, the Eisenhower program would require local districts to provide a 1:2 match; the local share of funds could come from other Federal programs such as Title I. The proposal would also permit States and districts to consolidate their applications, further enhancing the integration of Federal efforts.

CHAPTER 2 BLOCK GRANT

Question. The House version of ESEA reauthorization includes a program very similar to the existing Chapter 2 block grant program. States and communities like this program because it provides a very flexible source of funding that they can use to meet virtually any educational need. Can Goals 2000 funding be used to meet some of these same needs? For example, could Goals 2000 dollars be used to purchase improved instructional materials?

Answer. A 1994 evaluation of Chapter 2 by SRI International found that, for the most part, Chapter 2 funds have not been spent pursuant to any real reform improvement plan. Goals 2000 would be quite flexible, but would ensure that Federal funds are used to support a local reform strategy. Goals 2000 funds can be used to implement State, district, and school reform plans that are developed at those levels by the people who know their needs, not to implement federally imposed programs. If those plans require new instructional materials, then materials may be purchased with them.

PROGRAM ELIMINATIONS

Question. One of your justifications for eliminating three vocational education programs that we appropriated almost \$50 million for in 1994 is that the activities supported by these programs may be carried out under the Basic State Grant. Yet you are requesting level funding for Vocational Education State Grants -- the same level as was appropriated in 1993, by the way. How are States to support new activities with a State grant that is declining in real terms?

Answer. The administration's request of over \$970 million for Vocational Education Basic State Grants, accompanied by our request of \$300 million for the School-to-Work Opportunities program, can be used to support activities

carried out under the vocational education programs the administration proposes to eliminate. For example, the proposed School-to-Work Opportunities initiative includes community-based organizations as eligible entities in partnership agreements. One purpose of the initiative will be to motivate youth and dropouts to stay in or return to school and strive to succeed by providing enriched learning experiences and assistance in obtaining good jobs; thus the needs of the population served by the Community-Based Organizations program can be addressed with either School-to-Work or Basic State Grants funds.

PRISON LITERACY

Question. What is the literacy rate among the prison population?

Answer. To advance national knowledge on the literacy skills of incarcerated adults, the National Adult Literacy Survey conducted interviews with some 1,100 inmates from 80 Federal and State prisons. The survey included only those adults incarcerated in prisons, because more than half the Nation's inmates are in these institutions and because prisons hold individuals for longer periods of time than either jails or community-based facilities.

The demographic characteristics of adults in prison were not representative of the characteristics of the total population. Incarcerated adults tended to be younger and less educated than adults in the Nation as a whole. Males made up 48 percent of the total population and 94 percent of the prison population. The racial/ethnic characteristics of individuals in prison were also different from the total population. Incarcerated adults were less likely to be white and Asian/Pacific Islander than adults in the total population; black, Hispanic, and American Indian/Alaskan Native adults were overrepresented.

Given the relationship between level of education and literacy and between race/ethnicity and literacy, it is not surprising that the prison population performed significantly worse than the total population on each of the literacy scales. In terms of the five literacy levels defined by the survey, the proportion of prisoners who performed at the lowest level on the prose, document, and quantitative scales -- 31 to 40 percent -- is larger than that of adults in the total population -- 21 to 23 percent. Conversely, the percentage of prisoners who demonstrated skills in the two highest proficiency levels is far smaller than the proportion of adults in the total population who performed at those levels. This means that only 4 to 7 percent of the prison population performed at Levels 4 and 5 -- the highest proficiency levels in the survey -- compared to 18 to 21 percent in the population as a whole.

The Department recognizes that more detailed information is needed on the literacy skills of the prison population and will release a follow-up report on this subject later this year.

Question. Which Department programs provide support for literacy training and basic skills education for the prison population?

Answer. This year the Department will spend some \$49 million for programs that provide educational services to individuals in correctional institutions.

- Under the Perkins Act, States must use 1 percent of their Vocational Education Basic State Grants funds to serve individuals in correctional institutions. This will total \$9.6 million in fiscal year 1995.
- Under the Adult Education Act, States are required to set aside at least 10 percent of their Basic State Grants funds for corrections education and education for other institutionalized individuals. Using reports provided by the States, the Office of Vocational and Adult Education estimates that States spend 75 percent of these set-aside funds for corrections education. The remaining 25 percent is used for education programs for other institutionalized individuals. Based on these percentages, States will spend approximately \$20 million on corrections education in fiscal year 1995.
- Under Literacy Programs for Prisoners, the Department awarded \$4.9 million in fiscal year 1993, will award \$5.1 million in fiscal year 1994, and has requested \$5.1 million in fiscal year 1995 for discretionary grants to correctional institutions.
- Under the Chapter 1 Neglected and Delinquent program, about 34 percent of the students, 20 years of age and younger, served by the program are in adult correctional institutions. We estimate that \$13.6 million will be spent on this population in fiscal year 1995.
- Under Vocational Education Demonstrations, the Department awarded \$2 million in fiscal year 1992 and fiscal year 1993 for corrections education demonstration projects and will award an additional \$2 million in fiscal year 1994.

Question. Do States provide such education as part of their rehabilitation programs?

Answer. Although we know from anecdotal evidence that most States offer literacy training and basic skills education as part of their rehabilitation programs, at present we lack data to support these observations. However, the Department recently funded a field-test of a correctional education data collection project that will eventually provide us with State-level statistics on correctional education activities.

In 1992 and 1993, the project contractor field-tested the following three survey instruments designed to obtain data on education provided to inmates of correctional institutions: Survey of State Adult Correctional Education Agencies, Survey of State Juvenile Correctional Education Agencies, and Survey of Correctional Education at Jails. The final report on the field-test, released in

February, found that States could almost uniformly provide information on whether they offered different types of educational programs, the number of facilities at which educational programs were offered, and who provided instruction in these programs. About 80 percent of the States could report on the total number of inmates participating in education programs. The field-test found that jails were able to provide less information on their correctional education offerings and funding sources than State agencies responsible for correctional education. Generally, this is because jails are short-term facilities with more limited education offerings and few staff responsible for providing education.

With the results of the field-test now available, the Department has a better understanding of the type of information that States can provide on educational programs in adult correctional facilities, juvenile facilities, and jails. The Department now plans to analyze data obtained from this field-test and, in the future, may use the Survey of State Adult Correctional Education Agencies and the Survey of State Juvenile Correctional Education Agencies to conduct more regular data collections.

PELL GRANT SHORTFALL

Question. We are pleased that the estimated prior-year Pell Grant funding shortfall has diminished to the point that it may be possible to fully pay it off with the 1995 appropriation. Given the difficulty of estimating Pell costs, however, isn't it true that the only way to prevent future shortfalls is to maintain the option of reducing awards if necessary?

Answer. Secretary Riley is committed to ensuring that the Pell Grant program operates on a "pay-as-you-go" basis under which annual appropriations are sufficient to meet expected demand. As you point out, however, it is difficult to develop precise projections of Pell Grant program costs. The Department has taken a number of steps over the past year to significantly improve our Pell Grant cost forecasting process, but there will always be a margin for error in any cost estimate that in a multi-billion-dollar program could lead to a significant funding shortfall. Without the option of reducing awards, the only ways to finance such a shortfall would be to borrow from future appropriations or request a supplemental appropriation. We would prefer to avoid both these alternatives.

As you know, the Higher Education Amendments of 1992 eliminated the Secretary's authority to reduce student awards using a linear reduction formula, when funds were insufficient. We are requesting that 1994 appropriations language permitting the Secretary to revise the payment schedule before the start of the award year be retained for 1995. This would enable the Department to consider additional data in projecting student demand for Pell Grants and, consequently, program costs, and to reduce awards as necessary to avoid a funding shortfall. We do not, however, anticipate the need to use this authority to reduce individual Pell Grant awards for academic year 1995-96.

FRAUD AND ABUSE IN STUDENT AID PROGRAMS

Question. A few months ago, a Senate Subcommittee held a series of hearings that revealed a substantial amount of waste, fraud, and abuse in the Pell Grant program. What steps are you taking to eliminate fraud and abuse by institutions participating in the Pell Grant and other student aid programs?

Answer. The Department has been criticized in recent years for its administration of the student financial aid programs. While many of the concerns raised are legitimate, our efforts to strengthen the Department's management have not received the same attention. These efforts have led to a significantly more rigorous review process. For example, we have doubled the number of initial institutional applications for participation in the student aid programs that are rejected from 44, or 17 percent, in 1990 to 87, or 35 percent, in 1993; we have increased the number of institutions denied recertification from 45, or 15 percent, in 1990 to 103, or 20 percent, in 1993. We have also increased the number of limitation, suspension, and termination (LS&T) actions taken from 70 in 1990 to 168 in 1993. Lastly, we have increased the level of institutional surety in cases where such is necessary to protect students and the Federal Government and switched the type of surety required from performance bonds to letters of credit, which are more readily collectible by the Secretary.

In addition to increased travel for program reviews, the Department will enhance its data base management system for tracking information on individual schools. The Postsecondary Education Participation System will consolidate data from all program participation applications and reviews to increase the efficiency of Department staff.

To restore public confidence in the student financial aid programs, we must continue to improve our administration and institutional oversight. Through the implementation of the new State Postsecondary Review program, we have enlisted the aid of the States in overseeing postsecondary institutions participating in the student financial aid programs. In 1995, we are requesting a funding increase of 65 percent for this program. The increased funding, from \$21 million to \$35 million, will permit States to increase the number of reviews they perform.

IMPACT OF HEA AMENDMENTS ON INDEPENDENT STUDENTS

Question. Please explain the reasons for the change in the treatment of independent students under the Pell Grant program resulting from the Higher Education Amendments of 1992.

Answer. The Higher Education Amendments of 1992 provide for a single need analysis to determine student eligibility for all Title IV student aid programs. This single formula replaced two separate formulae previously used for Pell Grant eligibility and guaranteed loans and the campus-based programs. In developing this single formula, which combines elements of the two previous formulae, a number of trade-offs and compromises were made. In general, the

new eligibility formula is more favorable to parents of dependent students and independent students with children. When all student groups are considered under this new formula, about three-fourths of all Pell recipients received the same or larger awards in 1993-94 compared to the prior year.

Question. Can you describe the impact of this change on independent students during the past two years?

Answer. Independent students who do not have dependents of their own are now expected to contribute a larger share of their incomes toward their postsecondary costs before receiving a Pell Grant. In large measure, this results from a reduction in the standard living allowance -- the amount of a student's discretionary income set aside when calculating the need for financial aid -- from \$6,400 to \$3,000. As a result of this change, Pell Grant awards were reduced or eliminated for many unmarried independent students without dependents.

Question. Does the Department believe any further changes are needed to ensure equity in the treatment of independent students?

Answer. No. While some students have been adversely affected by the changes in the need analysis methodology, many others have benefitted. We believe that any increases in Pell Grant funding should be used to increase the maximum award -- as we have proposed in our 1995 budget -- which benefits all eligible students.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

STATUS OF HEAF TERMINATION

Question. It is my understanding that the Department has nearly completed the termination of the Higher Education Assistance Foundation (HEAF), the guaranty agency that failed several years ago, costing taxpayers over \$200 million. Can you tell us exactly where this effort stands?

Answer. The Higher Education Assistance Foundation concluded operations on March 31, 1994. As part of the wind-down, HEAF transferred \$300 million to the Department. The defaulted student loan portfolio was also transferred to the Department for collection. If the Department is able to match its historical collection performance on this portfolio over the next six years, the net result of the winddown will, contrary to the \$200 million cost statement in the question, reduce program costs by approximately \$70 million.

Question. Is it the Department's intent to re-capitalize what remains of this entity and have it either begin to guarantee new loans or take over the portfolios of other guarantors that might be terminated in the future? If so, why is such an expenditure of Federal funds necessary when there are over 40 existing guarantors which could take on these functions?

Answer. The Transitional Guaranty Agency, Inc. is a not-for-profit agency that was established by the individual members of the new HEAF board of directors. It is not an extension or continuation of HEAF. The transition guaranty agency will serve, only at the Department's request, as a servicer of guarantee portfolios and as a guaranty-agency-of-last-resort. Other existing guaranty agencies that have the capacity and willingness to assist the Department in the transition will be given an opportunity to do so before we turn to the transition agency. The transition guaranty agency is not designed to compete with the other guaranty agencies, but instead is intended to perform those functions that other guaranty agencies choose not to perform.

INCOME CONTINGENT LOAN REPAYMENT

Question. The Department is charged with implementing an income-contingent loan repayment system by July 1, 1994, for the Federal Direct Student Loan Program. What is the status of that effort? Would you provide us with the cost estimates of each of the options the Department is considering? For each of those options, will they be cost-neutral over the life of the loan?

Answer. Policies for income contingent and other alternative repayment plans are still being developed in preparation for ongoing negotiated rulemaking sessions. We anticipate publishing a notice in the Federal Register by May 31 that will specify these alternative repayment plans, which will be available to borrowers in the first year (1994-95) of the Direct Loan program. This notice will be the basis for the Notice of Proposed Rulemaking (NPRM) that will be negotiated with the higher education community later this summer. This NPRM will describe the Department's recommended alternative repayment plans for the second (1995-96) and subsequent years of direct lending. After accepting and reviewing public comment, a Final Rule will be published by December 1, 1994.

We anticipate that the availability of alternative repayment schemes, especially income contingency with a maximum repayment period of 25 years, will ease the student loan repayment burden and result in fewer defaulted loans. In fact, we believe that the use of alternative repayment plans by borrowers will ultimately be cost neutral with respect to loan program expenditures. That is, we expect that the savings resulting from fewer defaults will approximately offset the additional costs associated with excusing borrowers from their repayment obligations after 25 years in repayment.

FEASIBILITY STUDY OF LOAN SERVICING BY IRS

Question. The Budget Reconciliation Act required that the IRS/ED feasibility study be completed by February 10, 1994. When do you expect the study to be completed and why the delay?

Answer. Since the legislation passed, the Department of Education and Treasury, with IRS participation, have been meeting to evaluate options for IRS involvement in student loan servicing and repayment. We also jointly convened focus groups to obtain the views of students, borrowers, key congressional staff,

and the financial aid community regarding income contingent repayment and IRS involvement in student loans.

By the end of May, the Department of Education will publish regulations for the 1994-1995 school year specifying the parameters for income contingent repayment and other Direct Loan repayment plans. These issues, and ways to involve IRS in student loan collections, are being discussed with interested parties on the Direct Student Loan Regulations Negotiated Rulemaking Advisory Committee in April 1994. The negotiations will define the framework of the regulations that are ultimately issued by the Department of Education. Since the negotiated rulemaking sessions will affect many specifics of the Direct Loan Program, additional time is necessary to include the most up-to-date information in our feasibility study. Accordingly, we expect that the report will be submitted to Congress in June 1994.

ADMINISTRATIVE PAYMENTS TO GUARANTY AGENCIES

Question. Your budget request for fiscal year 1995 included \$345 million for Federal administrative costs associated with direct lending, including \$152 million for administrative expense allowances to guaranty agencies, which is estimated to be 1 percent of new loan volume.

Does the Secretary intend to insure that these allowances, formerly known as the administrative cost allowances (ACA), will be paid in a timely fashion during fiscal year 1995, and will payment be based on the same formula that is currently used? If not, what specific criteria will you use to determine payment levels?

Answer. The Student Loan Reform Act of 1993 eliminated the administrative cost allowance, fixed at 1 percent of new loan volume, and instead authorized "transition support (including administrative costs) for the expenses of guaranty agencies in servicing outstanding loans and in guaranteeing new loans" as part of the general authorization of funds for the administrative expenses of the Direct Loan program. Because of the short lead time and in order not to unduly disrupt the industry, the Department used the former ACA formula for fiscal year 1994 transition support, i.e., 1 percent of new loan volume, although it reserved the right to take an alternative approach if required by a particular agency's circumstances.

In a recently released statement on transition strategy for lenders and guaranty agencies, the Department stated that it intends to offer continued transition support to maintain a strong guaranty agency network, although not necessarily at a level sufficient to ensure every agency's survival. Since both the guaranteeing of new loans and the maintenance of the existing portfolio generate substantial costs for the agencies, and commitments will decline at a faster rate than outstanding portfolios as a result of direct lending, the former ACA formula does not properly match the subsidy with the costs. It is obvious that a change in formula is necessary to achieve the objective of maintaining a strong guaranty agency network.

Accordingly, the Department is presently considering both the aggregate amount of and funding formula for the transitional support for future years and expects to announce its decision this spring so that the guaranty agencies have adequate time to plan. Whatever the formula for fiscal year 1995, the Department will make the payments in a timely fashion and will continue to reserve the right to deviate from the formula in particular cases.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

DIRECT LOAN PROGRAM STAFF REQUIREMENTS

Question. In fiscal year 1995, you are requesting 130 new staff positions to implement the new Direct Loan program and to manage the transition from the Federal Family Education Loan program. Am I correct that this will bring the staff total for the Direct Loan to 350?

Answer. Yes, the 130 new positions we have requested for fiscal year 1995 would bring the total staff for the Direct Loan program to 350.

Question. What are your long-range projections for staff required to manage the Direct Loan program?

Answer. We project that a total of 520 staff will be required to fully implement the Direct Loan program and manage the transition from the Federal Family Education Loan program through fiscal year 1998.

Question. Will current staff working with the existing loan programs be able to transition into these new jobs, or will you be required to hire outsiders with more expertise in banking matters to fully manage the program?

Answer. For the most part, current staff working on the Federal Family Educational Loan program (FFEL) will have to continue to work in that area for the next several years. It will be possible to transfer a limited number of staff as the FFELP program proceeds through the transition into Direct Loans. In addition, we are examining how we do our work in all areas to make it more effective and efficient. These efforts, together with concerted retraining programs, will also allow us to move current staff into Direct Loans. However, we will also have to hire from the outside in order to ensure that the resources necessary to manage Direct Loans are available. We are looking for people with skills in a number of areas such as systems design and development, policy analysis, training, and accounting and financial management. Our first priority is to recruit for these positions from the financial aid community, thereby gaining the advantage of an institutional perspective in the implementation and operation of Direct Loans.

INSTITUTIONAL ABILITY TO REMAIN IN FFEL PROGRAM

Question. A number of institutions have indicated that they are not interested in participating in the Direct Loans program due to increased

administrative burdens at the campus level and the fear of exposure to liabilities in the event of program violations. Will these institutions be allowed to continue to participate in the Federal Family Education Loan program if they conclude the Direct Loan program is not appropriate to meet their needs and the needs of students on their campuses?

Answer. A number of institutions have expressed concern to us about the administrative burden that direct lending will impose. Schools not wishing to participate in the Direct Loan program will be able to continue in the FFEL program. We are concerned, however, that institutions make decisions after having obtained all the facts concerning participation in the Direct Loan program. We believe that the administrative burden on institutions will actually be less in the Direct Loan program than in the Federal Family Education Loan program. We will continue to correct the inaccurate and misleading information that has been distributed by the opponents of directing lending.

TRANSITIONAL GUARANTY AGENCY

Question. The Department of Education recently announced the establishment of a new guaranty agency, referred to as "Transitional Guaranty Agency, Inc." to assist in the transition from the Federal Family Education Loan program to the Federal Direct Student Loan Program. What functions do you anticipate the Transitional Guaranty Agency, Inc. will undertake during the next two years?

Answer. Initially, and solely to provide a modest cash flow to support core staff, the transition guaranty agency will collect on Chapter 13 bankruptcy loans. These are loans on which the borrower is required to pay a reduced percentage over some period of time. The agency will also service a small number of accounts that were not eligible to be transferred from HEAF to another guaranty agency. More importantly, however, the transition guaranty agency exists to serve as a fallback option for the Department in the event we need an entity to service guaratee portfolios of guaranty agencies that choose to cease participating in the FFEL program or to provide guarantees on new loans if other guaranty agencies choose not to perform those functions.

Question. What are the total estimated Federal costs associated with the agency's operations?

Answer. The Department provided the transition guaranty agency with an initial Federal advance of \$750,000 to be used as start-up capital. That advance must be repaid by September 30, 1995. According to the agency's projections, that is probably all the funds that the Department will be required to advance to the agency before it can generate revenue sufficient to cover expenses. Therefore, it is unlikely that we will make any further advances or expenditures.

Question. Did the Department undertake a comparative economic analysis of the cost of establishing a new agency as compared to using an existing agency to perform these functions prior to making the decision to start a new agency?

Answer. No. Since the Transitional Guaranty Agency, Inc. is an agency-of-last-resort that will provide guaranty agency servicing of student loan guarantee portfolios and provide new guarantees if other guaranty agencies either cannot or will not perform those functions, a comparative economic analysis of that type was not appropriate.

ESTIMATED DIRECT LOAN DEFAULT COSTS

Question. What is the Department's estimate of the default losses in the Direct Loan program over the next five years? What factors are this estimate based upon?

Answer. We estimate that Direct Loan default costs will be \$6.1 million in fiscal year 1995, rising to \$34.9 million in fiscal year 1996, \$113.5 million in fiscal year 1997, \$258.1 million in fiscal year 1998, and \$467.3 million in fiscal year 1999. These estimates include costs associated with loan forgiveness as well as defaults. These default estimates are proportional to default estimates for the Federal Family Education Loan program. All estimates are based on an analysis of historical data.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until 9:30 a.m., Thursday, March 24, when we will meet in SD-138 to hear testimony from the Secretary of Labor, Robert Reich.

[Whereupon, at 12:20 p.m., Tuesday, March 22, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 24.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1995

THURSDAY, MARCH 24, 1994

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Kohl, Specter, Hatfield, Cochran, and Gorton.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF HON. ROBERT REICH, SECRETARY

OPENING REMARKS OF SENATOR HARKIN

Senator HARKIN. Good morning. The Subcommittee on Labor, Health and Human Services, and Education will come to order.

Today is the last of three hearings with Cabinet Secretaries within the jurisdiction of this subcommittee to discuss the fiscal 1995 budget.

It is a pleasure once again to welcome Secretary Reich to the subcommittee today to discuss the fiscal 1995 budget for the Department of Labor. Secretary Reich has a distinguished career in academia and public service, and now in his current position has quickly reinvigorated the Department of Labor.

Following Secretary Reich's testimony, we will hear from a panel of the Department's Assistant Secretaries.

For fiscal year 1995, the President is requesting \$11.5 billion in discretionary funding for the Department of Labor, a net increase of \$928 million, or 8.8 percent more than last year's level.

Highlighting this budget is more than \$3 billion in investment spending for a variety of President Clinton's employment initiatives. Heading up this package is \$1.5 billion for a new and consolidated worker training program; nearly \$1.15 billion for an additional expansion of Job Corps; \$150 million to expand the national system of school-to-work transition; \$250 million for one-stop shopping; and \$9 million to continue the worker profiling program.

Mr. Secretary, this investment package includes a number of important and worthy programs. Again I would be negligent if I failed to bring to your attention and to your colleagues in the Cabinet that the investment package that is at the heart of the President's budget is in dire jeopardy. The problem is the tight budget caps passed by the Congress last year, and it is likely the budget squeeze is going to get even tighter especially with the Exon-Grassley amendment that was adopted and we are running with that right now.

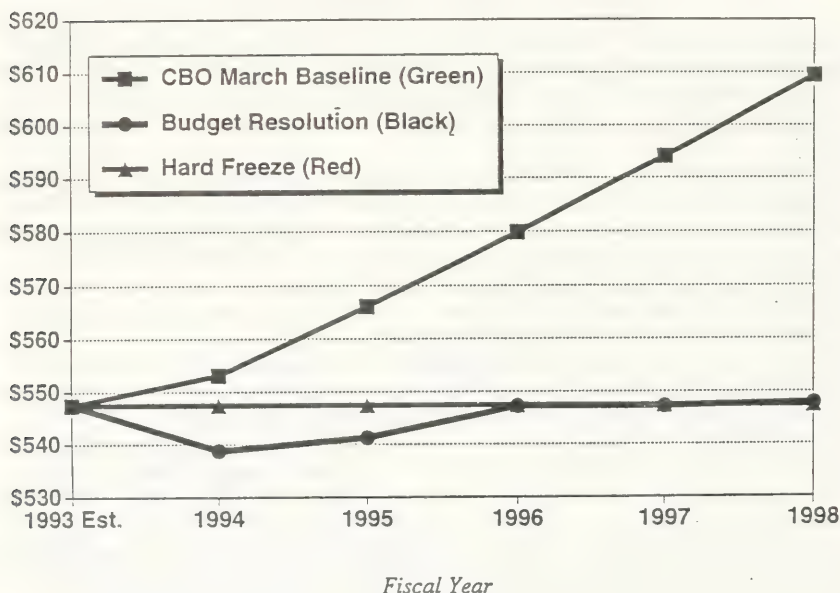
Before you begin your testimony let me just go over some of the problems we have here. I have these charts, I have had them up during every hearing I have had previously so you may have seen these charts before.

The real source of the problem is outlays. If you look at the chart starting on my far right, Mr. Secretary, it says discretionary outlays. You see the problem there. The March baseline in green is going up. Our hard freeze is the red line and we are actually down to the black line right now. So as we look at those out here the baseline goes up, you stay at that red line. That is what I call the outlay squeeze that we have coming up.

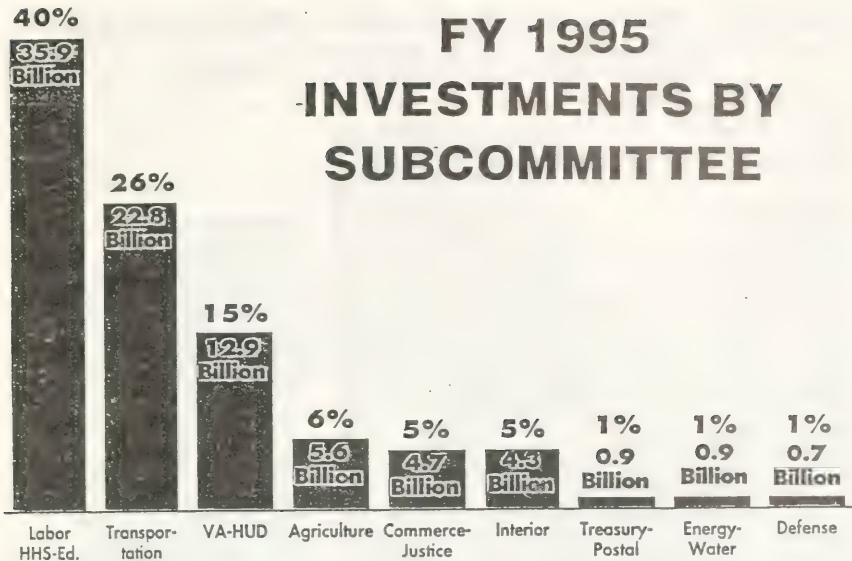
Forty percent of the President's investment package falls within the jurisdiction of the subcommittee, and that is the middle chart over there; 40 percent in this subcommittee, I think 26 percent in transportation and then on down. So the bulk of it really does hit this subcommittee's jurisdiction pretty hard.

Discretionary Outlays

(Dollars in Billions)



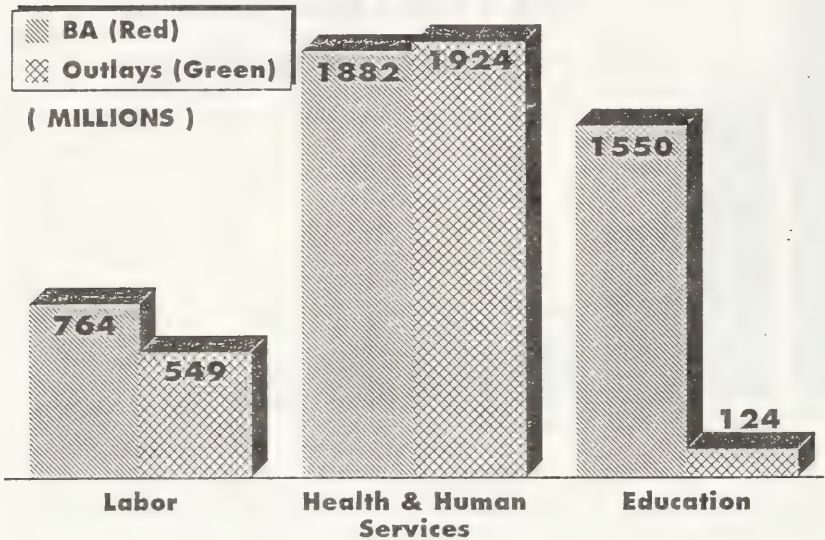
FY 1995

INVESTMENTS BY
SUBCOMMITTEE

The next chart shows, for example, the investment increases. Let's just talk about this chart on the far left over there. We can see the BA and the outlays for the different divisions within this subcommittee. Here it is \$764 million in BA and \$549 million in outlays over next year in the investment package.

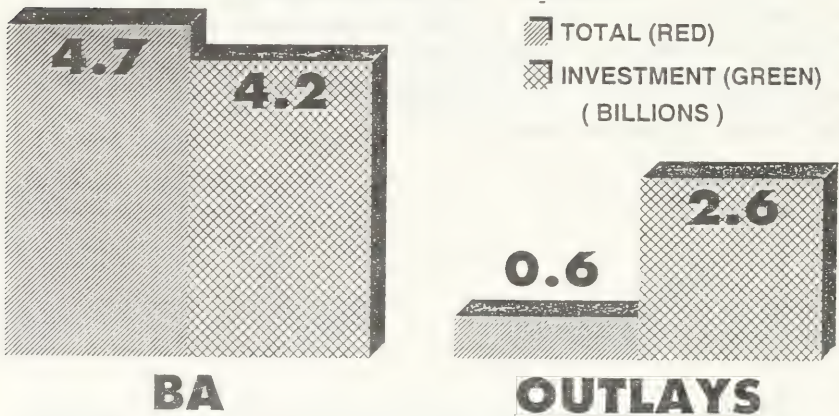
On this side, I think I skipped the one on the far left—well, the one on the far left lists all of the programs in your Department as the investment package. It is the middle chart that really tells the tale. Basically what we are looking at, if we look at the total investment package on the right there in outlays of \$2.6 billion but the total that we have of \$0.6 billion shows that we have a gap of about \$2 billion. So we have got a \$2 billion outlay gap this next year coming up that we have to somehow close.

LABOR - HHS - EDUCATION INVESTMENT INCREASES OVER FY 1994



LABOR - HHS - EDUCATION INVESTMENT INCREASES OVER FY 1994

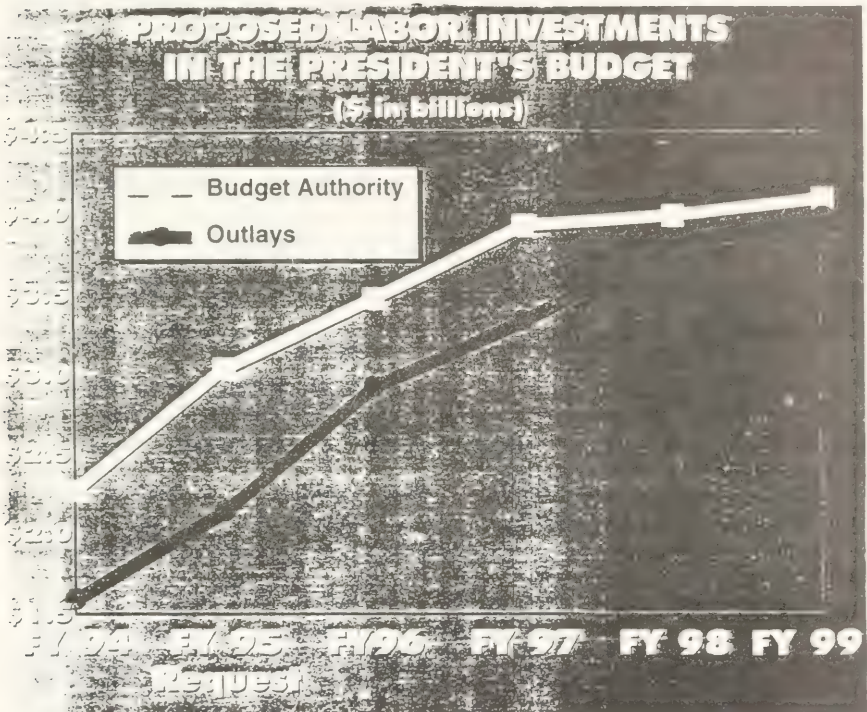
(Discretionary BA and Outlays)



Source: Office of Management and Budget (OMB)

Now we do have a number of different programs that were zeroed out in this budget by OMB but again that does not even come close to filling up that \$2 billion gap here between what we have and what we are asked to invest in the \$2.6 billion so we just have a big gap, a \$2 billion gap.

The last chart over there is kind of interesting; it shows where we are in terms of the investments in the Department of Labor for fiscal year 1994 of \$1.5 billion. You see by fiscal year 1996 we just about dealt with that in outlays. Quite frankly I don't know where they are going to come from because I don't see them outlaying here. How we are going to get the kind of outlays that we need for about \$3 billion in fiscal year 1996?



That is the squeeze that we have. You know as well as I do, Mr. Secretary, we have talked about it outside of this room. If we don't find the new outlays next year, I don't know what is going to happen to the investment package. You know I feel as strongly as you do about the investment package; it is needed if we are going to get this country moving. If we are going to have the educated work force that is needed globally, job training and retraining so we get our workers up to speed, we have to make the effort. If we don't, they are going to eat bread and water. You are much more eloquent in stating that than I am.

I am concerned that this budget noose is just going to keep pulling us tighter and tighter and strangle these programs that the President wants to have. So again we need to work together to make sure that we get the highest allocation possible so that we can preserve the investment initiatives, again while working to protect the Members of the Senate. A lot of the programs that the President has asked to be zeroed out are programs of Senators, and I am sure Members of the other body feel very strongly about.

Some of those just are not going to be zeroed out at all. They may be reduced a little bit but they won't be zeroed out.

So that is just basically a graphic look at the gap in the numbers we are looking at. I quite frankly, right now at this point in time, don't see our way out of it, unless we get the allocation that we need.

Having said that, Mr. Secretary, you don't have to repeat what you know all too well. I look forward to working with you to try to get the allocation that we need so that we can close that \$2 billion gap.

We will leave the record open for any opening statement by Senator Specter.

OPENING STATEMENT OF SENATOR MARK O. HATFIELD

I recognize at this time Senator Hatfield, the ranking member of the entire Appropriations Committee.

Senator HATFIELD. Thank you, Mr. Chairman.

I ask that you place in the record, you have left it open for Senator Specter, the ranking member of this committee, whatever comments he has.

Mr. Chairman, I also join you in welcoming Secretary Reich here this morning to this hearing.

I would only just make one or two observations in the form of opening comments and then, Mr. Secretary, I will have questions that I may have to submit to you in writing rather than remaining here throughout the hearing.

The observation I would like to make is that we have, as you know, a very difficult problem in the Northwest as it relates to our Federal workers and rather than just looking at that as a regional problem which many regions have other problems that are unique to their regions, this is especially significant nationally because we are in the process of moving toward a possible reauthorization of the Endangered Species Act, an act that I cosponsored and strongly supported in its original intent if not certainly in the ways it has been administered in every case.

Last Congress in the last year of the Bush administration when we were reauthorizing the Job Replacement Partnership Act, as you know I proposed an amendment to that act to recognize that across this country with thousands of listings under the Endangered Species Act in a process that it did represent a very unique and special category for displaced workers. I was proposing that there be a title or at least a recognition for such unemployment and such relocation of workers.

Secretary Martin, your predecessor, and both the managers of the bill feeling that the situation was rather fragile politically speaking in getting the reauthorization asked me not to pursue that amendment. Secretary Martin also under the discretionary funding found \$7.5 million to identify earmarked for test programs for certain workers. The State has applied for and received \$5.8 million, I believe, of that \$7 million plus, and it has been working but of course on a very, very inadequate scale.

Now, Mr. Secretary, we have of course been very much aware of your interest in this. Under title 3 you have made additional commitments that you would like to be able to fulfill, and they will be

in terms of the paperwork required. In the President's Northwest economic initiative dealing with things like timber workers, we also have the need to move quickly on that and waivers are terribly important.

I want to say that we have received extra cooperation from your regional office in the Northwest but there is concern both in your regional office and on the part of the State government that the central office may not be quite in tune with the uniqueness of this need to not only have money support but to have the waivers necessary to expedite and reduce the timeframe that is normal in those situations.

I just want to make the observation that I would urge again that this be a matter of highest priority for you in terms of your staff and the staff here in Washington.

One other quick observation and that is I have been long involved with farmworkers and seasonable workers in my State. Much of our agriculture is dependent on harvesting. I am proud to say that many years ago we were the first State to undertake migratory legal legislation which helped these workers in the manner of pay and education.

So I am a little bit—more than just a little bit interested in knowing the rationale for the reduction of that account in your proposed budget by some 8 percent, \$7 million, because that migratory labor necessity is still very high in our area and other parts of the country as well.

Mr. Chairman, that concludes my observations and remarks.

Senator HARKIN. Senator Gorton.

Senator GORTON. I have no remarks, Mr. Chairman.

OPENING REMARKS OF SENATOR THAD COCHRAN

Senator HARKIN. Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you. I just want to join you in welcoming the Secretary to our committee. I remember the appearance he made before us last year with pleasure. We discussed a number of issues with him then, including school-to-work initiatives and Job Corps Center location and construction. I want to just say that if I have to leave to go to a Defense Appropriation Subcommittee, I hope you will understand it is not because of a lack of interest in your comments or your testimony.

I have questions on some of these subjects and I would like to submit them for the record, Mr. Chairman, in case I won't be here to ask them personally.

Senator HARKIN. Certainly.

Senator COCHRAN. Thank you very much.

Senator HARKIN. Thank you, Senator Cochran.

Senator HATFIELD. Mr. Chairman, the reason I have to leave is it is one of those rare opportunities where, as a minority member of the Senate, I have been asked to preside at a hearing on another committee so I don't want to miss that opportunity.

Senator HARKIN. If you like doing that, I have an offer you can't refuse.

SUMMARY STATEMENT OF SECRETARY ROBERT REICH

Mr. Secretary, thank you again very much for being here. Please proceed as you so desire.

Secretary REICH. Thank you, Mr. Chairman and members of the subcommittee. I will with your permission submit my formal testimony for the record and proceed.

I am aware, as is every member of this administration, of the enormous burden and responsibility placed on this committee. Mr. Chairman, as you pointed out, the bulk of the President's investment budget is here in this subcommittee as it was last year, and there is a simple reason for that: because human resources are so key to the Nation's future.

You have heard the President on this point. You have heard many of us say precisely the same thing. You have said it, many members of the committee have said it, and that is that in this new world of competition the key resource of the Nation is its people. If we fail to invest in our people and fail to invest in our workforce, we are going to fail competitively.

Last year about 70 percent of the President's overall investment budget was financed Governmentwide, but because there were so many investments in this particular subcommittee's domain, a relatively smaller proportion of those investments were funded. In fact, only 35 percent of the President's original 1994 budget was fully funded.

And the reason, again you put your finger on it, Mr. Chairman, is because so much of the responsibility and burden is in this subcommittee. We will do everything we possibly can to help you and other members with regard to assuring that this subcommittee gets adequate funding to meet the President's goals.

If I may just for a moment give you some background and context. Allow me to just quickly move over here and give you a little background.

Senator HARKIN. Please.

JOBS RECOVERY

Secretary REICH. I think these issues need some context and this is the good news. We are in a jobs recovery and are creating on average about 150,000 net new jobs a month. Now that is net, notwithstanding appropriate downsizing, timber problems, defense downsizing and all of the other changes in the American labor force.

We have two major problems to deal with. Mr. Chairman and members of the subcommittee, the problems are getting worse, not better. The first problem is the widening gap between those who are prepared for this new economy of high technology and those who are not. This is very disturbing and it is a very sudden trend. It began gaining force in the 1980's but you can see that for both men and women the gap between the college educated and the noncollege educated is widening very quickly.

Beginning in the late seventies you can see a widening by one-third. This is directly correlated to education and training and skills because you can see people who have had some skill beyond high school, even if they do not have a degree or a 2-year college

degree, are doing considerably better than people without further training. We have got to make sure that all of our young people have that opportunity to prosper in the new world economy.

The School-to-Work Opportunities Act is one important point of beginning because it guarantees, when up and running, that all young people will have an opportunity, not just to graduate from high school but also to get some skill beyond high school so that they can get a footing in the world of work even though they don't have a college degree. We should not be living in a world in which a college degree divides the winners from the losers.

As I have gone around the country over the past year and looked at those programs, I have seen that many States have the beginnings of a practical program of school-to-work transition. They are terrific programs, but they need additional resources; they need an overall framework; and they need some momentum and leadership from Washington. That is what the School-to-Work Opportunities Act is all about.

SKILLS AND WAGES

I also want to point out a fact that is often hidden from public view and that is that not only are wages increasingly correlated with skills, as you can see in this chart, but also employment is increasingly correlated with skills.

In 1993 when we were still struggling to come out of a recession, college graduates on average had an unemployment rate of 2.9 percent. Now I am not suggesting that that is good. Ideally everybody gets employed. College graduates, however, are very vocal and very articulate, and you would have thought perhaps that the unemployment rate was much higher.

On the other hand if you look at the high school graduate with no skills, no training, nothing beyond high school, the rate was 6.2 percent last year. If you look at less than high school, it was 10.7 percent.

If you go beyond the issue of less than high school, if you simply look at our central cities, young people who have dropped out of high school who never formed any connection with the labor force, you are seeing rates of nonemployment much higher than 10.7. In fact, in many of our central cities in this country, you are seeing 50 to 70 percent of the young people out of school who have no jobs and no relationship with the job market. I know that Congress is now debating the crime issue. There is a direct correlation between lack of jobs and crime.

This chart shows the relationship between skills and earnings in a slightly different way, but it points out something that I want to bring to the subcommittee's attention. You see that for people with below average earnings, the highest level of education most of them have reached is just high school. This is, I think, very important from the standpoint of the Labor Department's initiative. We have a significant number of people with above average earnings who do not have a college degree, but who have some postsecondary training or some employer training. Postsecondary training, skills training, on-the-job training, or employer training are becoming increasingly important to get that above average job even if you don't have

a college degree. That's good news, but we have got to make sure that people know about it.

People ask me around the country, well, training for what. I have talked with employers in every major city in this country who tell me we need trained and skilled people.

In Chicago I met with people in the plastic injection molding business and in the spring-coil business. We can't get, they said, the skilled people we need. In East Los Angeles, I met with people who needed skilled people to do mobile electronics, to link up private branch exchanges in office towers. They said we don't need college graduates, we need people who have some skills.

I met with young people, many of whom have been gang members in many of those major cities, who are learning those skills and 80 to 90 percent of them were being placed in good jobs, in those so-called high technology fields. It is not impossible; it is being done, despite inadequate and poorly organized funding.

Senator HARKIN. I hate to interrupt you but are these employers saying that they just can't afford the training necessary for these young people to get jobs?

Secretary REICH. Yes; the employers, many of them as large companies, are shrinking. Much of the employment growth is in small- and medium-sized firms. The small- and medium-sized firms very often cannot afford the training and even if they could, they are concerned that, once trained, they will leave and go to work for a competitor.

STRUCTURAL UNEMPLOYMENT

Our first problem, then, is the increasing gap between the well trained and the poorly trained both with regard to earnings and funding. The second problem we are seeing is structural unemployment. The rate of long-term unemployment is increasing dramatically. In the 1990's, persons unemployed for 6 months or more are 16.5 percent.

The last data we have show over 20 percent of the unemployed to be long-term, having used up their unemployment insurance. The point is people are having a harder and harder time getting the next job because the old jobs are not coming back. It is as simple as that.

Usually after a recession you can get the old job back. People are not getting their old jobs back again this time. In fact, 44 percent of people who lost their job in the four prior recessions were on lay-off, appropriately expecting to be recalled. This past recession, only 14 percent on layoff were expecting to be recalled, meaning that 86 percent were permanent job losers.

CORPORATE DOWNSIZING

And this is not just disadvantaged. Americans at all income levels are experiencing higher rates of structural unemployment because corporate downsizing is not going to stop. In fact, over the past couple months we have seen a higher rate of downsizing than we have seen even during the recession. Over 180,000 jobs were lost in the past 2 months because of corporate downsizing.

Probably if the rate continues, over 1 million jobs this year will be lost because of corporate downsizing. Corporate downsizing is not bad necessarily, but the point is that all Americans were affected. If you add on the defense downsizing and regional problems like timber and other changes that are occurring in this economy, Americans as never before have got to change jobs.

This goes back to the point I was making before about metropolitan poverty areas. Just to underscore that point, look at black teenagers, look at white teenagers, and look at Hispanic teenagers. You have enormous rates in our central cities of unemployment.

The President's budget requests for 1995 square with everything that I have just said. In fact over the past year I have gone out across America trying to figure out what works to help Americans get good jobs. I looked in every major city. I looked at every major program that does seem to hold promise. The result is our budget request for 1995 for assistance for workers who lose their jobs given what I just said about the growing problem in every State, in every district.

BUDGET INCREASE

We are requesting an increase from 1994 to 1995 from \$1.1 billion to \$1.5 billion. It is a \$347 million increase, 31 percent. That is critically important to American workers who are finding themselves besieged by structural unemployment as never before.

Job Corps, a program that is this year celebrating its 30th anniversary, is a program that works for disadvantaged kids. It is an expensive program costing about \$20,000 a child. But I will tell you something, I have seen those centers and I have looked at those studies. We have key programs that work in terms of the public getting a big pay off. Every dollar invested in a kid in the Job Corps pays off in terms of a child who is not going to be a criminal, who is going to go to college, who is going to get a good job, and who is going to be a full and productive member of society.

That is a good investment. We are asking for an increase of \$117 million, and that is part of the President's broad plan, and I am sure supported by many people in Congress, maybe on this subcommittee, to expand our Job Corps.

For summer youth, we are asking for an increase of \$168 million. Last year's program was not as big as we wanted. We did have a new ingredient, however, that proved to be very successful and that was the educational component. About one-third of the young people in that program got some education over the summer. The critical need over the summer for many of the disadvantaged young people is to make sure that they don't fall backward, that they don't forget by September much of what they gained in the classroom by June. So that learning component in the summer jobs program is important. Last year we had two disadvantaged young people for ever single slot for which they were eligible for a summer job.

Right now, again I don't want to overstate the case, this body is debating a crime bill. There is no better anecdote to crime than a job. I challenge anybody to come up with a better anecdote to crime than a job. Last year two disadvantaged young people were eligible

for every one place that we had. This is a good and important program.

Senator HARKIN. What will that increase do for the duration of this summer?

Secretary REICH. The increase is not going to do too much in terms of the numbers of young people. I wish we could afford more. We need about approximately the same with our educational enrichment component. That is vitally important.

School-to-work is another vitally important program. We talked about it a moment ago, the young people who are not going on to college. The President is investing and is asking for 1995 for \$150 million, and that will be matched by the Education Department's \$150 million. Secretary Riley and I have worked very hard on this program. It has gone through the Senate, has been voted in the House, and it is in conference right now. I hope and expect that that will be on the President's desk very shortly.

One-stop career shopping is part of our effort to consolidate and make much more convenient all of the unemployment insurance, the job training, and all of the reemployment services. As I travel across the country I have seen in Baltimore, St. Louis, Hamden, CT, and in many of your States, an attempt to pull together unemployment insurance and reemployment services, and make sure the people get it early. This is the foundation stone of the President's Reemployment Act which you just introduced. One-stop career shopping is a vital and important component of that to make sure that there is one place where you can get all of these services. You don't have to go to the Unemployment Office and wait in line. You don't have to go to the JTPA office. You are treated as a real customer.

Other employment and training has a total increase of \$74 million.

ENFORCEMENT INCREASES

Let me go to our increases in enforcement as well. As you know, Mr. Chairman and members of the committee, the Department of Labor's budget was cut by about one-third during the 1980's. Unfortunately, many of the enforcement objectives were sacrificed in that cutting. We have new responsibilities this year with regard to job safety and health, with regard to target enforcement, and that includes the Family and Medical Leave Acts.

We have a project to provide a periodic role of management and review of the Federal employee compensation benefit system that is also a new responsibility. We are also asking for additional enforcement help with regard to mine safety. We have a good record. We want to maintain that record; it is important. With pension and welfare benefits, given that we have seen a lot of big problems in multiple employer welfare plans, we also need some additional enforcement resources and litigation support. Our total \$66.7 million increase in budget authority and also 355 people are needed in the enforcement area.

I want to bring your attention to one very important aspect of enforcement, and that is we are putting more and more of the resources in the field moving responsibility downward and getting rid of a lot of administrative layers. Later on this morning you will be

talking to some of the Assistant Secretaries with enforcement responsibilities and our instructions to them are to get out into the field to go after those few bad apples, to be a responsible enforcement. I want to emphasize responsible enforcement rather than coming up with lot of command and control.

REEMPLOYMENT ACT

Let us finally say a few words about the President's proposed Re-employment Act of 1994. I mentioned it in connection with one-stop shopping already. We intend to consolidate all of the programs dealing with dislocated workers. Regardless of why you lost your job, you should get help, and this goes back to my introductory remarks. As never before Americans have got to change jobs and we have got to give them help.

Right now we have a very disorganized, fragmented system. You must show that you are eligible for one of these fragmented programs. It should not matter. We all have a stake in making sure that Americans get that next job and get that next job quickly and easily through one-stop centers and that they also get reemployment services, not just training.

For some people training is not necessary, but they do need good information about where are the jobs, what are the jobs, what skills are necessary for those jobs, and what training is necessary for those skills. They also need job search assistance, and we have seen around the country that job search assistance pays off.

Under the Reemployment Act, we expect that about 750,000 individuals will be helped in 1995. We intend by the year 2000 when this is fully operational to be able to provide assistance to 1.3 million Americans out of the 2.2 million who lose their job. Our information is that about 1.3 million need help getting the next job to benefit from reemployment decisions.

Again I want to stress, Mr. Chairman and members of the subcommittee, it is not just training. We will provide training when it is linked closely to a job, but also other necessary assistance. Training is only about one-third of the program.

PREPARED STATEMENT

That concludes my formal remarks. I want to just end by stressing once again that the American workforce, even though jobs are coming back, faces two great problems which are becoming larger and which must not be ignored. The worst problem is the widening gap in earnings and employment between those who are well educated and well trained and those who are not. The second is the difficulty many Americans are having getting the next job. We must do something about these problems.

Thank you.

[The statement follows:]

STATEMENT OF ROBERT B. REICH

Mr. Chairman and Members of the Subcommittee, I appreciate this opportunity to appear before you today to discuss the Department of Labor's fiscal year 1995 budget proposals, and to discuss the major investments in the Department's fiscal year 1995 budget and how these investments contribute to the President's overall plan for long-term economic growth.

Our budget proposals build on the foundation for long-term growth and prosperity that was laid last year. You will recall that when I appeared before this committee almost a year ago, I emphasized the central need for workforce investment as a strategy for economic recovery. A year ago, our Nation's economic picture was cloudy, with escalating budget deficits, a lingering recession, and a stagnated economy.

Today, the picture is significantly brighter. Nearly two million jobs were created in the first year of the Clinton presidency. Some 1.7 million were in the private sector, about 70 percent more than in the years 1989 to 1992. The economy grew at a rate of 2.9 percent during 1993.

During 1989-92, it grew at a rate of 1.4 percent, and inflation increased at the lowest rate since 1986—this means that we have laid the groundwork for a strong, steady recovery. And there is a clear downward trend in budget deficits.

But serious social and economic challenges remain. I want to begin by setting the specific—and difficult—choices this budget represents in the larger context.

Even as overall unemployment is down, the problem of long-term unemployment remains acute. The average length of unemployment spells in the 1990's is higher than it was the previous four decades. Despite the recovery, the average length of a jobless spell hit their third highest annual levels since the end of World War II. In 1993, less than twenty-five percent of persons who had lost their jobs expected to be called back to their old jobs after a period of lay-off. For the other seventy-five percent of those who had lost their jobs, no recall to their old job was expected—representing the highest percentage of permanent job loss ever registered.

The increasing challenges of a global economy, defense downsizing, technological advances, and corporate restructuring all add fuel to anxieties about job security. It is more critical than ever that we maintain our commitment to building a national workforce strategy that includes all our citizens. Increasingly, workers without skills will find their options shrinking, as more and more old jobs become imperiled by global economic integration and technological change. Fewer Americans can count on holding a single job throughout their careers and the unskilled face worsening odds for sustainable prosperity.

The challenge this Administration and this Congress face is to attack our most pressing problems within the context of a vigorous budget—and to fund what works. The proposed budget request for the Department of Labor in fiscal year 1995 is \$36 billion in budget authority and \$34 billion in outlays. The amount now before this committee includes \$10.1 billion in Federal funds and an additional \$3.7 billion in trust fund limitations. A total of 17,910 full-time equivalent (FTE) staff is requested for accounts which provide staffing for employment and training, worker protection, labor, pensions and employment standards, and statistics programs.

This Administration is committed to investing in America's workers. In total, the Department's share of the Administration's human resources investment program has increased \$1 billion—from \$5.5 billion to \$6.5 billion. Investing wisely means investing in what works—and it means the courage to look candidly at what doesn't work and to invest elsewhere. We need to keep asking these difficult questions. And as the answers come, we need to have the discipline to act on them. We must provide our young people with the necessary skills to obtain good first jobs, and we must ease the transition of displaced workers quickly into new jobs, and finally create better jobs over time for all Americans through new initiatives to enforce workplace safety and health and other labor laws. The Department will continue to follow this three-pronged workforce investment strategy.

First jobs.—For young people, preparation for their first full-time job can be critical. It can mean the difference between a career that holds promise of growth and increased earnings, or a job with uncertain opportunities and income growth. Under the first job component of the Department's workforce investment strategy, the Administration proposed the School-to-Work Opportunities Act, which has now passed both the House and Senate, to provide a national framework for allowing states to create programs to smooth the transition from the educational system to the working world, including curriculum reform and on-the-job experience. The required training and work experience will lead to a high school diploma and, for many, a certificate of successful completion of at least one year of post-secondary education, and an industry-recognized credential. Currently, unlike young people in Japan or Germany, for example, young Americans entering the workforce after high school make their way into their first jobs with little guidance, direction, or support. We know that people learn better when they see the connection between what they are learning and why they need to learn it. People learn better when they can work closely with an expert, ask questions and apply the academic lessons. The Department's fiscal year 1995 request for this important new program is \$150 million with an equal amount requested by the Department of Education. This amount rep-

resents a significant increase from the \$50 million provided in fiscal year 1994. These funds will be used to build on effective approaches already underway at State and local levels to ease the transition from school to work for three-fourths of American youth who enter the workforce without four-year college degrees.

The first jobs component also includes increases for Job Corps programs and summer employment and training. We continue to believe that young people whose needs may be the greatest should be among the first to receive assistance.

Our investment proposals under first jobs calls for an additional expansion of one of our most effective programs—the Job Corps. Our fiscal year 1995 budget request includes an increase of \$117 million for a proven winner for disadvantaged youth. These funds will provide for six (6) new centers and the completion of the eight (8) centers that will begin in 1994. When the current expansion is complete in 2004, the program will have increased from 112 to 162 centers, and from 42,500 slots to 62,500 slots. This comprehensive residential training and education program for severely disadvantaged youth has been successful in increasing earnings, employment, and educational achievement, while decreasing welfare dependency. There is no doubt that Job Corps is expensive. There is also no doubt that it works and it is well worth what it costs.

Our fiscal year 1995 budget request for first jobs also proposes \$1.1 billion for the Summer Youth Employment and Training Program. This amount includes \$184.8 million for summer jobs in addition to the \$682.3 million currently available for calendar year 1995, and \$871.5 million for calendar year 1996. The increased funding will allow maintenance of the 1994 participant level of 623,000 in calendar years 1994–96. Reviews of last summer's program indicate that the young people involved were well supervised, performed real and useful work for the community, and often received substantial education benefits.

Also, included in the fiscal year 1995 budget request is \$598.7 million for youth training grants to support 322,000 economically disadvantaged participants both in-school and out-of-school. A recent study confirmed mounting signals that conventional short-term training programs for disadvantaged youth fail to have any positive impact on their job prospects or earnings. So our fiscal year 1995 budget pares back youth training grants by 9 percent (or \$60 million) while we develop new, more effective approaches. We have requested \$25 million for the Youth Fair Chance Program, which concentrates a diversity of services in specific economically depressed areas to help reduce the high school dropout rate, crime, and teenage pregnancy. The fiscal year 1995 budget request, along with funds previously appropriated, will support grants to 21 economically disadvantaged areas.

New Jobs.—Each year about 27 percent of our Nation's workers move to new jobs, whether to advance careers or rebound from a job loss. The new jobs component of our workforce investment strategy will help experienced workers move from one job to the next and ease fears about job change particularly for those who lose their jobs through no fault of their own. Reemployment, not unemployment, will be the centerpiece of our economic renewal.

In order to improve the current dislocated worker assistance effort, which is rigid, ineffective, and serves only a small percentage of the 2 million workers in a categorical fashion, the Administration proposed the Reemployment Act of 1994, which is founded on sturdy evidence about what works. Our current unemployment insurance (UI) system no longer delivers what American workers need. Today, UI still helps millions of workers through short-term income support, but the current system simply is not set up to help workers build new skills and find new jobs. The proposed legislation will consolidate, expand, and improve this patchwork of categorical programs which targets a subset of the dislocated worker population, such as workers displaced by trade, defense downsizing, or environmental initiatives. Our fiscal year 1995 budget request of \$1.5 billion for worker readjustment will emphasize services with proven effectiveness and will serve approximately 750,000 workers in 1995, building to 1.3 million upon full implementation in fiscal year 2000. This represents an increase of \$347 million or 31 percent over the fiscal year 1994 level.

The proposed Reemployment Act of 1994 will have six basic components:

First, there will be early outreach and information to provide rapid response and referral of UI applicants who have been identified as at-risk of long-term unemployment through worker profiling to re-employment services. We are requesting \$9 million in fiscal year 1995 for automation support for the profiling initiatives.

Second, quality re-employment services will be provided for all dislocated workers, including eligibility review and referral to appropriate programs, individual assessment, counseling, and job search assistance. Most dislocated workers just need some basic help in assessing their skills and in planning and conducting their job search.

Third, and closely related to the second component, is quality labor market information. Information is a key component of any re-employment effort. The labor-market information component will expand access to good data on where the jobs are—and which skills these jobs require.

Fourth, One-Stop Career Centers will provide a single point of entry into the employment and training system. Our resources will act as seed money to help States plan and implement programs that streamline access to the full-range of these services. Our fiscal year 1995 budget request is \$250 million for this initiative, an increase of \$150 million over the fiscal year 1994 level.

The fifth component of the Reemployment Act of 1994 will be long-term retraining, including basic skills, classroom, and on-the-job training for eligible participants who need it to get a new job. The evidence shows that short-term training programs do not work for dislocated workers. The proposed legislation will offer workers who need long-term training programs with up to a year and a half of income support and support services to enable workers to complete training and launch new careers.

And the sixth component is accountability. Programs that work are customer-driven—they offer customized service, quality information, and meaningful customer choice. Programs that work are obsessive about accountability and results.

In addition, the new jobs category also includes \$12.4 million for the new Skills Standards Board, as authorized by the Administration's Goals 2000: Educate America Act, to spur the development of a national network of voluntary skill standards.

The New Jobs category includes \$1.1 billion for JTPA Adult training grants to increase the earnings and employability of economically disadvantaged adults and, ultimately, to reduce welfare dependency. This request is expected to result in service to an estimated 480,000 participants in 1995. For the Older Americans Community Service Employment Act, we are requesting \$396 million to provide part-time work opportunities for an estimated 91,200 unemployed, low income individuals aged 55 and over. The New Jobs category also includes \$918.3 million for the Employment Services, a nationwide system of over 1,700 state offices providing no-fee services to individuals seeking employment and to employers seeking workers.

The Department total in the First and New Jobs categories for programs for the disadvantaged totals \$4.1 billion for both youth and adults. This represents an increase of \$467 million or 13 percent above the fiscal year 1994 level.

Preparing young people for their first job and experienced workers for new jobs is necessary to restore America's promise of prosperity, but again it is not enough. The third component of our three-pronged workforce investment strategy includes initiatives to promote better jobs.

Better Jobs.—Overall, the Administration is pursuing three goals which support better jobs. The first focuses on the economy as a whole and includes stimulating investments, investments in new technologies, expanding retraining programs, and opening global markets to American made products. The second and third focus is on the job site by promoting the high performance workplace and enhancing enforcement of workplace laws. With respect to promoting high performance workplace practices, I have established a new organization, which is the Office of the American Workplace. This Office will conduct research and carry out initiatives designed to promote increased competitiveness of American industry through a more effective partnership between management and workers and in many other ways to enhance productivity and quality.

An essential component of the strategy for better jobs is blocking the "low road" to competitive advantage—a road paved with substandard wages, discrimination, health and safety violations, to name just a few—through energetic and strategically targeted enforcement of key labor and employment laws. To achieve the third goal under the better jobs component, we have requested \$66.7 million and 355 FTE to finance an enforcement initiative to better meet the Department's responsibilities to enforce workplace rules. These additional resources would enable the Department to address responsibilities under new regulations and recent laws, such as the Family and Medical Leave Act. Also included are increased inspections of small mines and enforcement of mine health issues, review of the periodic roll in the Federal Employees Compensation Act program, and a program of coordinated, high profile interventions that focus on repeated and egregious violations of key labor laws.

Our enforcement initiative will provide resources for more compliance staff and investigations; but, going one step further, we will reinvent and restructure enforcement activities within the Department. Our reinvention efforts are based on recommendations of the Vice President's National Performance Review. Major components in this area include expanding the use of modern information technology—putting more computers into the hands of front-line workers and economizing on scarce litigation resources by expanding the use of Alternative Dispute Resolution.

There are many other activities planned to improve compliance, fortify respect for labor laws, and shift the cost of compliance.

One area of enforcement that deserves special attention is occupational safety and health. Our fiscal year 1995 request for the enforcement initiative includes \$18 million and 132 FTE for improved oversight of occupational safety and health. This request will provide a modest enhancement for a program which is severely underfunded and operating under a legislative mandate that is more than twenty years out of date. Also, the Administration will work with Congress to improve occupational safety and health through legislative action to reform the Occupational Safety and Health Act.

The Department is also taking measures to ensure that hard-earned pension benefits of America's workers and retirees are safe and secure. The proposed Retirement Protection Act of 1993 would increase the pension security of workers and retirees by requiring faster funding of underfunded pension plans and giving the Pension Benefit Guaranty Corporation (PBGC) more compliance authority. The bill would require underfunded plans to give participants better information on plan underfunding and PBGC guarantees. The bill also would require the worse-funded plans to pay a greater share of premiums by lifting the cap on the variable rate premium.

While my three-pronged workforce investment strategy does not specifically mention all of the Department's very important programs, please be assured of my deep commitment to all of those programs as well, most of which fall within the better jobs component. For example, our request for \$5.2 million and 29 FTE for the multi-year Consumer Price Index (CPI) Revision project. When completed, this project will provide new market baskets of goods and services as well as improvements in collecting and processing data for the CPI and for surveys which support the CPI.

I mentioned last year that I was committed to improve upon all of the Department's important programs by launching my own program to reinvent the Department. To date, considerable progress has been made, such as the efforts that are underway in the enforcement area. But there is still much work to be done. We are committed to the principles outlined in the Vice President's National Performance Review. Among other things, we have established a strong management/union partnership to guide our reinvention efforts to improve customer service to the American worker. We will be reducing supervisory/staff ratios, empowering front-line workers, and we will be taking an objective look at how we perform our work in all programs to seek more efficiency and economy to enable us to work more effectively within existing employment ceilings and budget constraints.

To support this massive undertaking, we have requested \$25 million for a Reinvention Investment Fund to finance reinvention proposals and other capital investments aimed at achieving savings from streamlining work processes. This fund will be self-sustaining because the funds will be paid back by the agencies with interest from the savings generated. We look forward to sharing our reinvention success, from projects and savings financed through this, in the future.

The Department's budget signals a major shift in policy from simply seeking to ease the pain of unemployment to actively promoting new and better jobs for the working men and women who are the backbone of our economy. This budget reflects the President's commitment to fiscal discipline in discretionary spending while recognizing the paramount importance of investing in working people in ways that boost their productivity and prepares them to adjust to economic change and compete successfully in global markets.

Once again, I am aware of the pressure on the Appropriations Committee due to the discretionary spending caps, particularly in this subcommittee. The President has made some hard and difficult choices to stay within these spending caps by generating the savings to finance his investment program, much of which falls within the jurisdiction of this subcommittee. With the President's strong commitment to his investment agenda and with Congressional support, I remain confident that we can find a way to accomplish these long-term public investments to improve American productivity and competitiveness.

Mr. Chairman, we at the Department believe that our investment proposals support the President's overall plan for economic growth. Along with the other priorities reflected in our fiscal year 1995 budget request, these proposals will enable us to increase the productivity of American workers and businesses and will make a positive difference in the lives and well being of America's working men and women. Only if we invest prudently in the American workforce can we strengthen our position in the world economy.

This concludes my prepared statement, Mr. Chairman. I would certainly be happy to answer any questions that you or other members of the Subcommittee may have.

BIOGRAPHICAL SKETCH OF SECRETARY ROBERT B. REICH

An advisor to business, government and political leaders, Robert B. Reich has led a distinguished career in academia and public service which has been marked by his lifelong examination of the effect of changing global economic realities on working Americans. According to *Fortune Magazine*, "no one is better than Robert Reich at describing the challenges facing America from the emerging global economy." *Fortune* named Reich among 25 individuals who are making the U.S. more competitive.

Reich's work on Bill Clinton's economic plan, "Putting People First," defined the central challenges of the American economy and proposed a comprehensive response. The response included tax incentives for capital investments targeted to new machinery and equipment and to small business, investment in the country's deteriorating physical infrastructure and a national commitment to invest in the workforce.

A faculty member of Harvard's John F. Kennedy School of Government, Reich is the author of seven books and some 200 scholarly and popular articles on the American economy and the emerging global economy. His more recent book, *The Work of Nations: Preparing Ourselves for 21st Century Capitalism*, examines the challenges the American labor force faces in a global economy and calls for a national strategy to upgrade America's human resources.

Clinton nominated Reich as Secretary of Labor on Dec. 11, 1992. "I named by economic plan Putting People First to highlight my belief that our nation can only become a high-wage, high-growth economy if we make a commitment to invest in the American people," said Clinton. "With his help, I believe we can bring forth a revolution in lifetime training and education of our workforce."

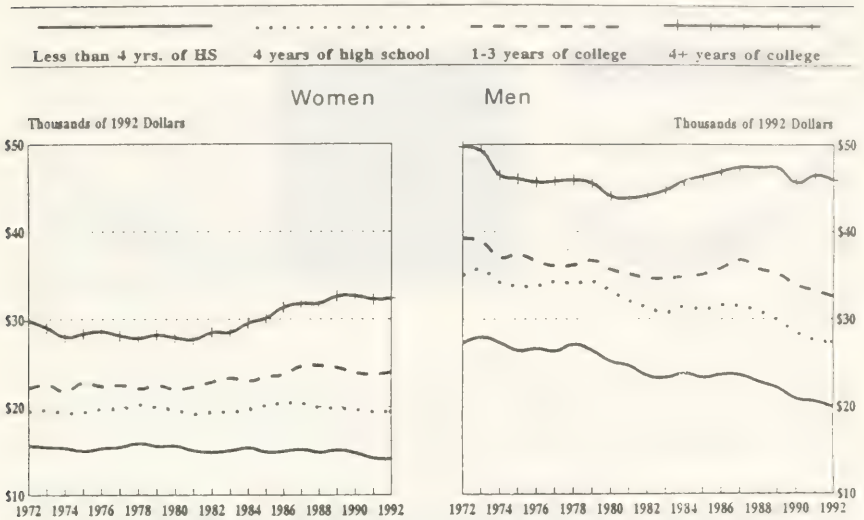
Born in Scranton, Pa. in 1946, Reich grew up in rural South Salem, N.Y. His parents owned two retail clothing stores. Reich graduated from Dartmouth College—of which he has been a trustee—and received a law degree from Yale. A Rhodes Scholar, he holds a degree in philosophy, politics and economics from Oxford, where his classmate was Bill Clinton. While at Oxford, he also met his wife Clare Dalton, now a law professor at Northeastern University. Their two children are Sam and Adam.

After graduating from law school, Reich clerked for the Chief Judge of the U.S. Court of Appeals for the First Circuit. During the Ford Administration, he served as assistant to Solicitor General Robert Bork. His next appointment in the Ford Administration was as assistant director of the Federal Trade Commission's Bureau of Consumer Protection, where he oversaw and evaluated the work of the bureau's regulatory efforts. From 1976 to 1980, he headed the policy planning staff of the Federal Trade Commission.

His articles appear frequently in *The Harvard Business Review* and *The Atlantic*. Reich is also a contributing editor of *The New Republic* and of *World Policy*; chairman of the editorial board of *The American Prospect*; a regular columnist for Japan's leading newspaper, *Nihon Keizai Shimbun*; a frequent contributor to *The New York Times* and other newspapers; a regular commentator on public radio's *Marketplace* and public television's *Nightly Business Report*. In May 1992, Reich co-authored and hosted the acclaimed PBS television series *Made in America*.

Earnings Gap Widening

Annual Median Income by Years of School

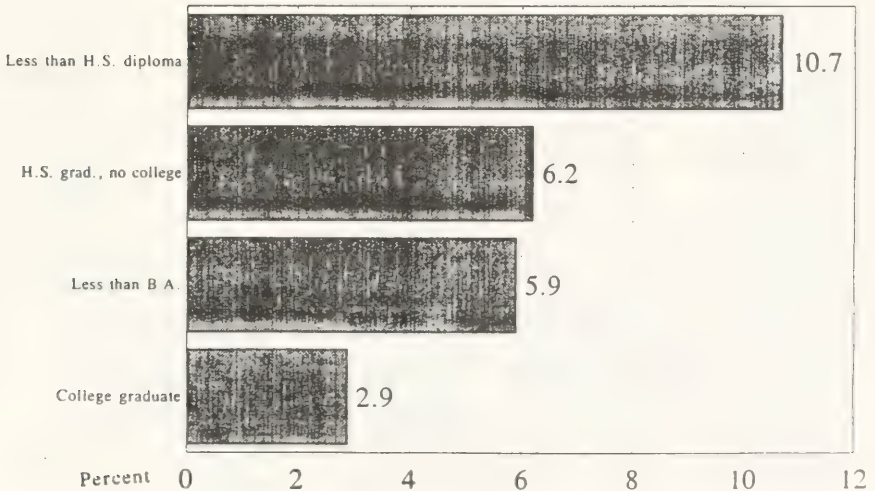


Source: Bureau of Census, Current Population Survey

Note: Workers 25 years and older, working year-round, full time. Data on educational attainment for 1991 and 1992 are not directly comparable to prior years.

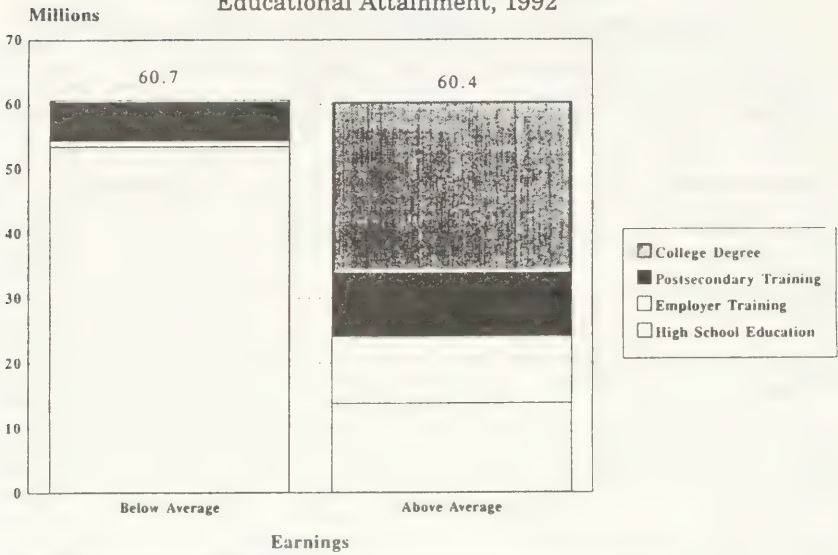
Unemployment Rates By Educational Attainment

1993 Annual Averages



Source: Bureau of Labor Statistics, Current Population Survey
Prepared: OASP/2.16.94

Occupational Employment By Earnings and Educational Attainment, 1992



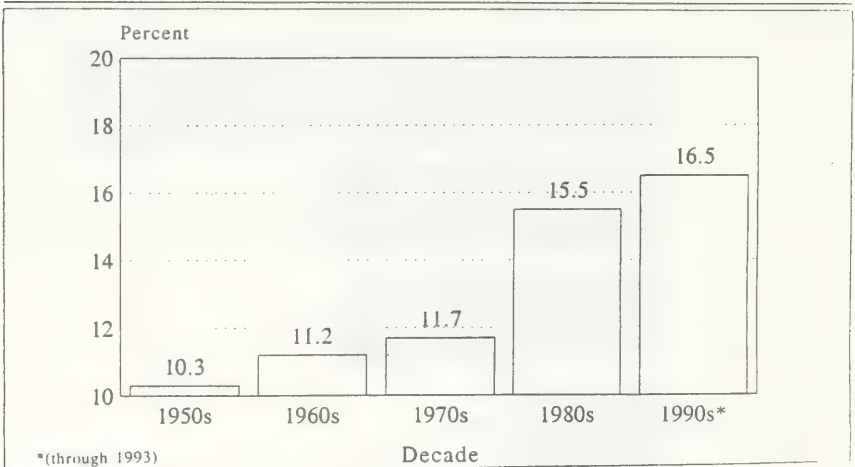
Note: Employment for each occupation is categorized by median earnings and usual education and training. Each earnings category accounts for approximately one-half of the total employment in 1992. This occurs because workers in each occupation were allocated to only one earnings category.

Source: Bureau of Labor Statistics

Prepared By: OASP 3/4/94

Long Term Unemployment is Increasing

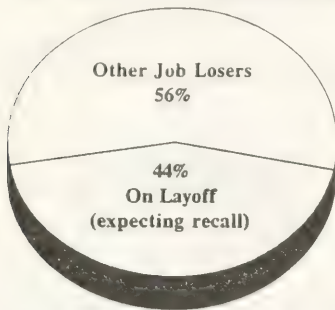
Persons Unemployed 6 Months or More as a Percent of Total Unemployment*



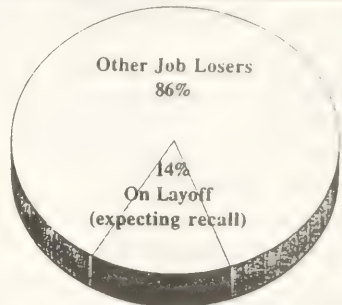
Source: BLS

Prepared by: OASP 3/7/94

Unemployed Not Expecting To Get Jobs Back



Average for Four Prior Recessions

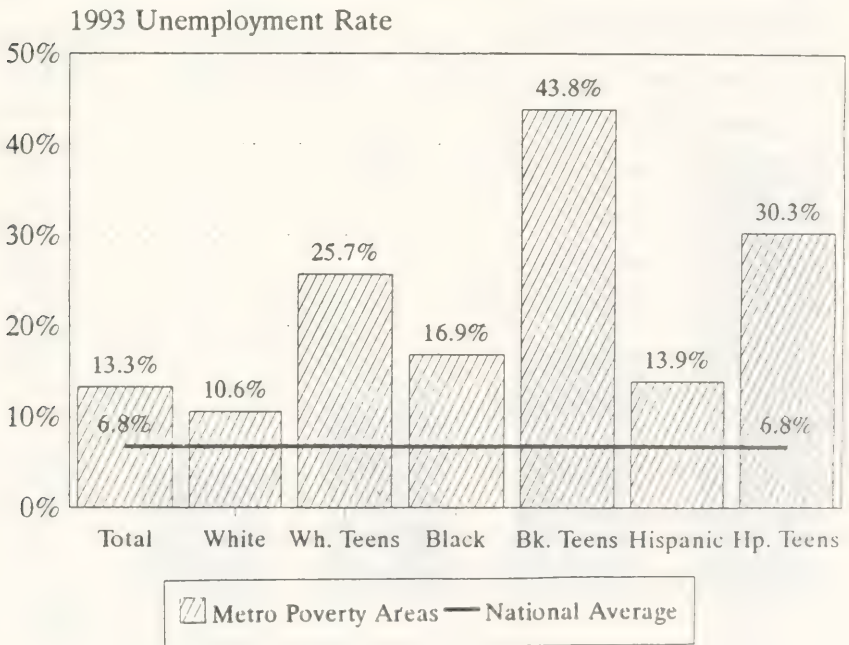


Recent Labor Market Contraction
July 1990-June 1992

Note: The National Bureau of Economic Research has determined that the recent recession began in July 1990 and ended in March 1991. However, the July 1990-June 1992 period is used for the comparison with earlier recessions because the number of job losers did not peak until June 1992, well past the official endpoint of the recession. In prior recessions the peak in the number of job coincident with the official endpoints.

Source: DOL/Bureau of Labor Statistics, Current Population Survey.

Unemployment Plagues Metro Poverty Areas



MAJOR INCREASES IN FISCAL YEAR 1995 BUDGET

(Budget Authority in Millions)

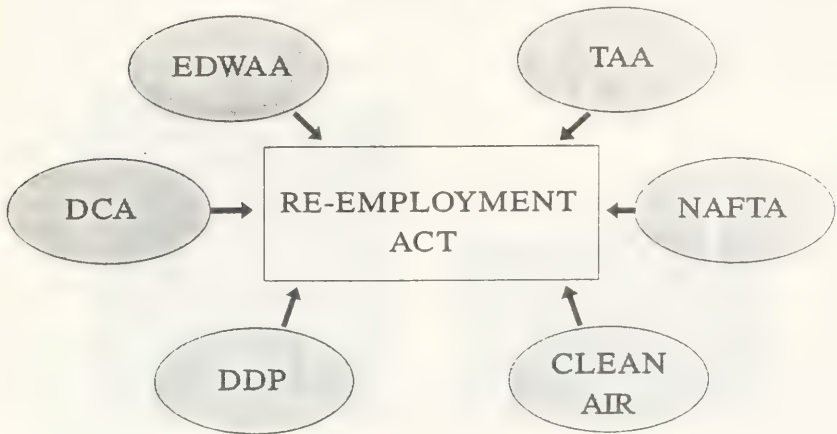
	FY 93	FY 94	FY 95	FY 95 Increases:	
				Amount	Percent
Dislocated Worker Assistance	\$651	\$1,118	\$1,465	347	31.0%
Job Corps	966	1,040	1,157	117	11.3%
Summer Youth	1,025	888	1,056	168	18.9%
School-To-Work	---	50	150	100	200.0%
One-Stop Career Shopping	---	50	250	200	400.0%
Other Employment and Training	2,368	2,328	2,402	74	3.2%
TOTAL	\$5,010	\$5,474	\$6,480	\$1,006	18.4%
TOTAL, DOL Discretionary Budget	\$9,954	\$10,596	\$11,708	\$1,112	10.5%
FTE, DOL	19,582	19,448	19,460	12	0.1%

ENFORCEMENT INCREASES IN FY 1995 BUDGET

(Budget Authority in Millions)

	FTE	AMOUNT
NEW RESPONSIBILITIES....		
Job Safety and Health	132	\$18.0
Targeted Enforcement		
(includes Family and Medical Leave)	40	1.2
FECA PRM Project	105	8.1
Mine Safety and Health	43	2.8
Pension and Welfare Benefits	25	5.1
Litigation Support	10	0.8
REINVENTION....		
Information Processing	--	26.3
Alternative Approaches	--	3.3
Alternative Dispute Resolution	--	1.0
TOTAL	355	\$66.7

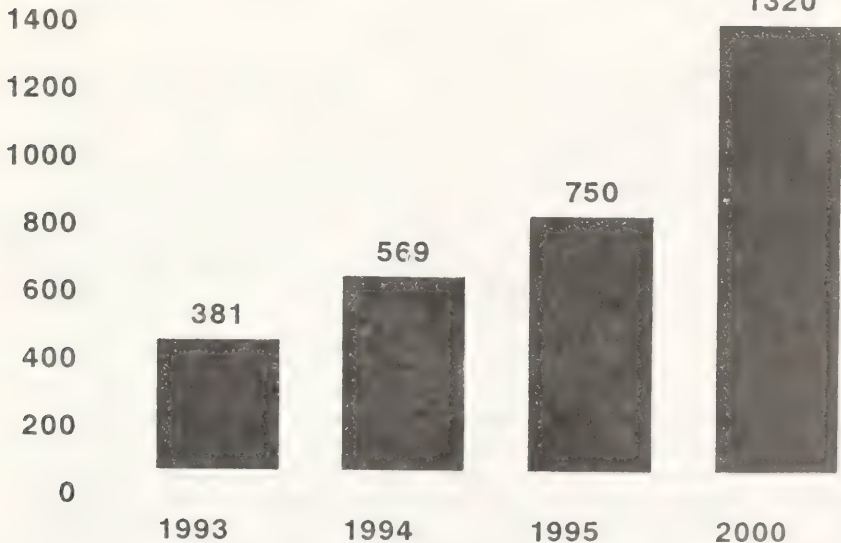
Re-employment Act Consolidates Six Programs for Dislocated Workers



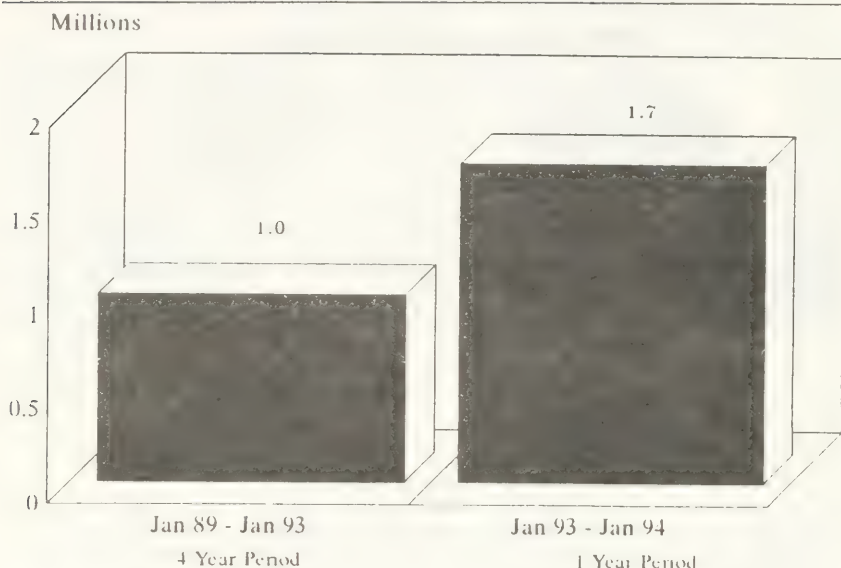
Programs: EDWAA - Economic Dislocation & Worker Assistance; TAA - Trade Adjustment Assistance; NAFTA - NAFTA Bridge Program; CLEAN AIR - Clean Air Employment Transition; DDP - Defense Diversification; DCA - Defense Conversion Adjustment

RE-EMPLOYMENT ACT PARTICIPATION FY 1993 - FY 2000

Thousands



1.7 Million Jobs Created During 1993 Growth in Private Nonfarm Jobs



Source: BLS
Prepared by: OASP 3/7/94

Senator HARKIN. Mr. Secretary, thank you very much.

Very eloquent statement on the employment situation. There is some good news as you say on the total net number of jobs.

JOBS INCREASE

Secretary REICH. The net number of jobs is going up, but the most recent poll shows 40 percent of Americans express their fear they are going to lose their job within the next 2 years. You go out there and American after American and worker after worker says, yes, jobs are increasing but why do I feel so nervous and insecure, and why am I working part time when I would rather be working full time? Why am I working temporary when I would rather be working a full-time job? We have got to deal with the problems of job change and the importance of getting skills.

PROGRAM CONSOLIDATION

Senator HARKIN. One of the things you pointed to was the consolidation of the training program. I want to take off on that just a little bit because we have been looking at that also here in the subcommittee and some of it goes beyond our jurisdiction and beyond the Department of Labor and other Departments. The General Accounting Office in January had more than 150 job training programs in the several groupings of programs serving the same population. Now you proposed consolidation of about six if I am not mistaken based on the work program.

Secretary REICH. If I may clarify that. Of those 150 programs, 12 account for about 80 percent of the money.

Point No. 2 is that the GAO study covers everything from programs in the Education Department to Job Corps intended for disadvantaged, to vocational programs in schools. We are talking about the entire education and training of Americans from the age of 12 all the way through retirement. So there are different needs, and our judgment is that the best way of consolidating is to use three things.

No. 1, consolidate all of the programs for people who lose their jobs who need new jobs.

No. 2, provide one-stop shopping so that a State may create centers in which all job training is accessible to that customer at one place. From the standpoint of the individual citizen, he or she does not care whether for accounting purposes or for programmatic purposes or for oversight purposes there is consolidation. That individual cares on the street at the individual site can I get access to all of these programs that I need.

No. 3, we are providing waiver authority and that waiver authority would also apply to the JTPA. Waiver authority would allow States, without reducing the amount of money going to the disadvantaged or to any other particular targeted group, much more leeway in coming up with creative solutions to responding to the needs of people for getting jobs. And hopefully, although we have not come to a final conclusion on this, even welfare recipients would be able to go to the same one-stop centers and get job search assistance, job counseling, and good information about where are the jobs and what skills are necessary.

We also need to know which training works. Right now any trainer can give training and does not have to report about success rates and who got what job and what it paid. We are going to require in the Reemployment Act that everyone who provides these kinds of services has to first provide a report on any individual, any consumer, any worker, about the record of that particular trainer.

Senator HARKIN. Mr. Secretary, I appreciate that. I just want you to know that we advocate creating administrative savings by consolidating some of the programs. You mentioned 3 percent of the money and perhaps you are right, and I am sure you are, that some of these cannot be consolidated for various reasons but to the maximum extent possible I would like to see what kind of administrative cost saving we can get by pulling as many as possible under one line of authority somehow. We will get that report today and obviously will share it with you to take a look at it and see what GAO says.

I don't know if we will get the welfare reform this year or not. I hope so. If we get the health care reform bill and get that through, certainly that is going to be next on our agenda or very high on our agenda after the reforms go through.

The President's upcoming welfare reform proposal, what is the relationship between your proposed funding increase for a health training program and the welfare employment? I am sure you are involved in that process. Will there be some linkage? Will there be some assuming under welfare reform or vice versa of adopting

these programs? How is that going to fit together with your proposal?

ADULT TRAINING

Secretary REICH. The President is seeking an increase for 1995 of 14 percent in adult training under the Job Training Partnership Act. That is based on a lot of research showing that the adult training parts of JTPA are working very well. We are showing that with regard to JTPA methods that we are providing longer term training, and longer term training provides the biggest benefit.

The one-stop centers I referred to in the Reemployment Act hopefully will be the places where even welfare recipients can come and get whatever job service assistance and benefits they want. We are going to make an effort to integrate the JTPA title II adult programs with what is called the JOBS Program so that the two population groups—

Senator HARKIN. Under you or under HHS?

Secretary REICH. We haven't made any decisions. The integration may be, and I hope it would be, to give the States maximum discretion in terms of how they want to integrate. You see, the point of welfare reform is to get people into work but also to get them to stay in work; 70 percent of people on welfare today will get into work and off welfare within 2 years. The problem is that most of those people fall back into welfare at some point in the future. The real challenge is to keep people off of welfare. That is why these programs are so important.

We are now serving under the disadvantaged adult JTPA program only 5 percent of the population that is eligible, the population that needs assistance in getting jobs and getting the skills necessary for getting the jobs. So there may be savings, but the universe is much, much larger than what we are trying to accomplish.

Senator HARKIN. What we are seeing from the subcommittee standpoint is that the people on welfare are eligible for the jobs program but what is happening is that States aren't spending their jobs money. People are shifting, and they are shifting more to JTPA. Consequently we have waiting lists and waiting lines for JTPA, and yet not all the money is being spent on the jobs program, I assume because of the States' matching funds. I don't know if you looked at that or not. It seems to me that if you are talking about putting together the jobs program, we have to look at why the States aren't using the jobs money. I mean that is not in your Department but it is something that we look at here. We have got these two programs and one has got a waiting list and the other one doesn't, and I think it is probably because of that matching money.

Secretary REICH. If I may, Mr. Chairman, that JOBS Program as it is now designed is only available to people who are AFDC recipients. The JTPA program is for the working poor, who are not necessarily, and in fact for the most part are not, AFDC recipients.

As I said, the universe of working poor who are in danger of dropping into AFDC is substantially larger than the program of JTPA adults can handle right now. So if anything, my judgment

would be that if we are doing something right to keep people off of welfare, we ought to continue to do it right.

I understand the drift of your question. You, as I understand, are asking if the States are shifting that JOBS money under JTPA because they don't want to pick up some of the national funds. We have got to at least investigate that and I agree.

Senator HARKIN. You should. Then the other part of my question is that you have got two jobs under administrative programs essentially trying to do the same thing. As you say, the JTPA is not jobs. I don't know exactly. Again looking at consolidating these administrative tasks and perhaps saving some money that way.

Secretary REICH. We are looking at that right now in an actual welfare program. About 25 to 33 percent of the JTPA adult participants are in fact receiving welfare. This is an overlap, but it is only 25 to 33 percent.

WELFARE REFORM

Senator HARKIN. Mr. Secretary, I just have one last question for you. You have been involved with the administration's considerable welfare reform efforts, a matter in which I have a longstanding interest and hope to take an active role in this final plan being adopted by Congress.

Obviously job training is a key component of welfare reform as you stated. What role will the Labor Department play in the administration's reform proposal, and what are your thoughts about how welfare reform should be financed given the budget rules that we are now operating under?

Secretary REICH. Let me get to the first and easier part of your question.

Senator HARKIN. I am just looking for guidance.

Secretary REICH. Welfare reform has several components, some of which are already on track and that is the earned income tax credit making work pay. I think with the history of this—

Senator HARKIN. Can I just say something about this. I have been in a number of meetings with both welfare workers, caseworkers and welfare recipients in developing this welfare plan starting at the bottom and working up. It came up at one meeting and I was shocked to learn that not only did the clientele, the clients, not know anything about the earned income tax credit, the caseworkers did not know anything about it.

So I began asking questions at the meetings I went to and I found that there was this lack of knowledge. No one was telling them that they were eligible for this. Finally after about the third time I sat down and penciled it out for a couple of people. What they were earning in this year, talking about the earnings from tax credit and what they would be eligible for, they had no idea that they were eligible for it. So somehow we have got to get this information out there; it is not being used.

Secretary REICH. Mr. Chairman, we have alerted all of our JTPA offices and our unemployment insurance offices and other offices to get the word out. We have given them all the information. But I think even beyond alerting the clients and individuals through these offices, we ought to mount a major campaign to make sure that people know this money is coming to them, because for many

individuals it is very important if they are at the bottom of the income ladder.

Senator HARKIN. We will let you take this up with Secretary Benson. I am just wondering if public service announcements on television might not be a good idea along that line.

Secretary REICH. I agree.

We also are moving toward another element of the program for welfare reform which is health care reform, guaranteed universal private health insurance. You know as well as I that one reason that at least some people say there is fear that if they get off of welfare they are going to lose their Medicaid and they will lose their health insurance.

Now those two critical elements are supplemented by one-third, and that is enforcing laws which ensure that the absent parent pays a fair share of the responsibility for bringing up a child.

A fourth piece is the training and job placement, and that is where we have been working very, very closely with HHS to ensure that our efforts already ongoing with the Reemployment Act are tightly coordinated with the job training and job placement efforts. We are still waiting on that. I can't give you a definitive point by point right now, but I can assure you that I have spent much of the last week and the week before, and the month before that working on the task force coming up with a welfare plan.

And finally, the issue is what happens after 2 years. After 2 years on AFDC we will have a transitional work program. We want to make sure that they will be paid by the job, not by the Government. That is a paycheck, not a check from the welfare office.

Your next question I think is more difficult, and that is the difficult question that surrounds many of these statements, how to pay for it. The administration is now assessing various alternatives in the context of enormous budget constraints.

Senator HARKIN. We have to look at that and how we are going to take care of all of these welfare proposals.

Let me just state one thing about the welfare proposal by President Clinton. I have talked with Secretary Slavin and I know what we have done in Iowa. I think we are making a gross error if we put in a 2-year time limit. You may look at it from a liberal standpoint, that that is too short a period of time. Quite frankly I think 2 years may be too much time. I think if you set a 2-year maximum, that becomes the minimum. People will stay on for 2 years. I think history will prove me right. Look at the past. Whenever we have had maximums, those become the minimum.

What I am going to propose in our welfare reform bill is that we have an individualized program, not one side against all. It has been our experience again in Iowa that people—most of the people don't need 2 years. They may need 2 months, 1 month, 5 months, 10 months, 1 year. The vast majority of people don't need 2 years and they shouldn't have that hanging knowledge that they can get 2 years. I think that will save us a lot of money.

Second, I think by dangling out there some aspect of a public service job or something like that, I think you go on for 2 years and then put them in some kind of a deadend public sector job that is supported somehow. Again I think it is not only going to cost us

a lot of money but we will not get the end result we seek and that is to get people in private sector.

Those are just two observations I have. We will talk more about that.

Secretary REICH. I would be delighted to and I am eager to talk to you and I am sure Secretary Shalala as well.

Senator HARKIN. Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Mr. Secretary, I join my colleagues in welcoming you here.

The subject that I had not intended to be a topic for discussion here I would like to put at the top of the agenda. Many years ago, shortly after the turn of the century, there was substantial Federal legislation to protect women and children from excessive hours of work. And it has come to my attention that there is another endangered category on excessive hours that I would like to broach with you and that is the U.S. Senate.

The Federal Government has frequently intervened to protect those who cannot or will not protect themselves. In this category there are a number of Senators in their eighties, some in their nineties and it may be that the Department of Labor could submit some guidance to the Congress as to what action ought to be taken. We almost ran right into your testimony time. If we had finished reading the last amendment which was filed, we would still be in session so you would not be able to testify this morning.

Senator HARKIN. Only to the extent OSHA worked for the Senate?

Senator SPECTER. Well, we might, depending on what the Secretary comes up with. I am not sure OSHA is appropriate; it might be mine safety.

Secretary REICH. We have a similar problem in the executive branch, Senator, although we don't work until 2 o'clock in the morning.

Senator SPECTER. Do you vote?

Secretary REICH. We tend not to vote.

Senator HARKIN. I have heard there was only one vote in the executive branch, the Director of OMB. [Laughter.]

LITERACY JOB TRAINING

Senator SPECTER. Perhaps second only to literacy training there is a flurry of activity on the so-called three strikes and you are out issue which has met with a very high decimal rate on both ends of Pennsylvania Avenue. My experience suggests that we are not going to get justice when we impose life sentences on career criminals simply by passing mandatory laws. The system will have an infinite number of ways of avoiding mandates from legislatures.

I believe that it is indispensable if we are to have the realistic chance of incarcerating career criminals for a while. There appears an opportunity for literacy job training because it is no surprise a person without a trade or a skill goes back to a life of crime. When the judge has that moment of sentencing it is a very individualistic manner and unless there is some showing that the individual has had an opportunity, the judge simply is not going to impose a life sentence.

I applied for years to the district attorney for Philadelphia to get an habitual offender's sentence for life. Some 40 States have had measures on their books with relatively little effect. Now suddenly there is a flurry of activity but it can be done in my judgment. We passed the law in 1984 to Federal law and it is a very valuable tool for law enforcement.

This morning at 3 a.m., the Senate accepted an amendment that I offered, and one of the three parts of that amendment provides \$100 million to prisoner literacy and job training programs. At this point I would like to insert the amendment into the record.

[The information follows:]

[From the Congressional Record, Mar. 23, 1994]

The second transfer is \$100 million for prisoner literacy, education and job training, and it is designed to take to come to grips with some realistic rehabilitation. That figure is by no means sufficient to deal with the problem in this country, but it would establish a fund for a demonstration project to see if something meaningful can be done in that line.

This is a legislation which I have proposed virtually every year since 1981, and it is designed to try to stem the growth of the career criminal in this country. It is also designed to try to set a realistic scene for the imposition of life sentences on the so-called three-strikes-and-you-are-out legislation.

We have heard a great deal of rhetoric on three-strikes-and-you-are-out, and it is my view, based on experience as a prosecuting attorney, that judges will not impose mandatory life sentences. Under our current system where they see the cycle of crime with recidivists coming back again and again, where it is no surprise that a functional illiterate without a trade or a skill will go back to a life of crime, in the sentencing situation, as I think the Presiding Officer knows from his experience as an assistant district attorney, the judge simply is not going to impose a life sentence.

But, if there were realistic rehabilitation after juvenile offenses, and after a first offense, and the individuals did not do better with rehabilitation, with literacy training, and job training, and after a second offense came back and committed a crime of violence—armed robbery, for example—then I think it is realistic to have judges impose life sentences.

The Federal armed career criminal bill, which was passed as one of my earlier initiatives in 1984, amended to include drug offenses in 1986, has been acknowledged as a very important tool for law enforcement. If we really came to grips with career criminals in America, we could reduce violent crime very substantially.

The National Commission on Criminal Justice Standards and Goals back in 1972 estimated that violent crime could be reduced by some 50 percent. And if we make a real effort with rehabilitation, literacy training, and job training, and the individuals fail at that, then I do believe we can realistically move to life sentences for career criminals.

The third item, Mr. President, on this amendment which would receive \$100 billion in funding, would be for prenatal care and pregnancy prevention.

MR. COHEN. Did the Senator say \$100 billion?

MR. SPECTER. I said \$100 million. If I said \$100 billion it was a slip of the lip. At this hour I might have said \$100 trillion. I think I said \$100 million, but I do know. Whatever I said, I meant \$100 million.

But I thank the Senator for the interruption, if not the suggestion. It sounds like a hollow tunnel. I thank the Senator.

The program which this \$100 million is designed to address, again, is a demonstration project to see if something can be done on this problem of enormous magnitude.

The leader in the Senate is the distinguished Senator from New York Senator Moynihan. If I might have Senator Moynihan's attention, I have been very much impressed with the clarion call which our colleague from the State of New York has made on the problem of rising pregnancies and unwanted children. It is a source of enormous problem in America which should have been addressed a long time ago. It is a very complex matter as to how to address it. It results in enormous costs.

In 1991, the most recent statistics available, the Federal Government spent some \$29 billion for AFDC, aid to families with dependent children, Medicaid and WIC payments. As to the families begun by teenaged parents, more than 1 million Amer-

ican teenage girls between the ages of 15 and 19 become pregnant each year, and there are some 50,000 low birth-weight babies born to teenaged girls.

I first saw a 1-pound baby in 1984 when I visited a hospital in Pittsburgh. It was an ominous sign, a child as big as a hand. It is a human tragedy, because those children carry those scars throughout their lives. It is a financial tragedy because the average cost is \$158,000 a child.

I introduced legislation on this subject back in 1985, and with the cooperation of both the Bush administration and the Clinton administrations, we have had a healthy start program which has done some good on prenatal care. It is a very important factor in planning health care reform because there are billions of potential savings there.

But this program of teenaged pregnancy is one which is long overdue in being addressed.

My colleague from Iowa, Senator Harkin, who chaired the Subcommittee on Labor, Health, Human Services and Education, and I have sat down with the Secretary of Health and Human Services, Secretary Shalala, and the Secretary of Education, Secretary Reilly, to try to find some answers here.

Secretary Shalala made the observation that her study showed that most teen-aged pregnancies occur between 3 p.m. and 7 p.m. And as Senator Harkin and I tackled the problems in this subcommittee, with the great shortage of funds—this \$100 million transfer is from consultants, and we have yet to really find out what consultants do. This \$100 million would be a tremendous aid in enabling us to structure some programs to tackle this very, very important problem.

So, in summary, Mr. President, this amendment takes a look at an account on consulting fees, \$2.1 billion, which is bloated and overspent, and it seeks a 19.5 percent reduction, and then seeks to tackle three very, very important problems.

The issue of assistance of low-income heat and energy is one of the most important ones that has been cut by the administration in a draconian way, and this would at least restore funding to last year's level.

The demonstration projects were \$100 million. That on prisoner literacy training and prisoner education would enable us to try to deal with a major problem, and, at least set the stage so that inmates who do not take advantage of realistic rehabilitation or do not succeed at it, then we would be able to impose life sentences on career criminals and make America's streets safer.

The \$100 million for prenatal care and pregnancy prevention would give us at least some start on this problem of enormous magnitude.

I yield the floor.

Senator SPECTER. I note that the Department of Labor has recommended to the House a youth crime demonstration program which looks somewhat similar to a program which I had proposed last year to the Department of Labor, but was advised that the administration was opposed to having an Office of Job Training for Prisoners put into the Department of Labor, and it ended up in the Department of Justice and it was accepted as an amendment to the Senate crime bill which is now pending.

If you have any awareness of that rejection by the administration from the Department of Labor, I would like to know why it was not thought appropriate to put it into the Department of Labor which seemed to me to be much better there than in the Department of Justice. It conforms to the amendment which is now for your program, the Department of Labor program, coordinating adjustments which is now in the House bill.

Secretary REICH. Senator, I don't. I will give you full credit for coming up with much of the original inspiration for this. The youth employment and skills pilot project which we have suggested in the House version of the crime bill does have many of the elements that you indeed came up with and it will target. And it is a pilot program designed to get some very good information which we don't have right now.

We can posit that there is an inverse correlation between the jobs and crime; that is, the more jobs, the less crime. We are going

to target, under this proposal, a few areas that we want to saturate. We want to make sure that these areas of very, very high unemployment, very high poverty, and very high crime are targeted to bring the youth unemployment down from 70 or 80 percent down to 20 percent and then evaluate and see what consequences there are with regard to crime.

It will be a competitive program; that is, various cities and locales can compete. There are going to be some criteria set up. We are not going to make the awards unless a region or a city is willing to put in some matching funds and do certain things as well. I agree with you. I think this is critically important.

Senator SPECTER. Mr. Secretary, I would like to develop that further with our staffs. If we are able to hold this \$100 million, I know the chairman, I know Senator Harkin will join me in an appropriate motion when the full Appropriations Committee meets that we have a contrary view expressed by the chairman of the Appropriations Committee to have the money allocated to the subcommittee so they can put that \$100 million into prisoner literacy training or job training.

I believe that if we did that and followed through on the results, it is very important to follow through the people that get rehabilitation training and see what happens to them in terms of success rate and also in terms of what happens to them on sentencing rate when they are recidivists. But it is necessary for public safety that we not have criminal fears. It is necessary for some humane treatment for the individual and it would certainly be a big step up in turning the high decimal record on three strikes and you are out into reality if such programs were in effect so that we could get large sentences when people have had a chance and failed.

Secretary REICH. Senator, if I may also, I am sure you are aware that for over two decades the Department of Labor has a credible bonding program which has very successfully placed young people and adults who come out of prison, in jobs that they could not have attained without some sort of a guarantee fidelity bonding with regard to their reliability. The default rate here is less than 2 percent.

Senator SPECTER. What do the bonding companies do? Are they active in ensuring that they won't withhold on their payments?

Secretary REICH. They are ensuring against employee thefts primarily or dishonesty. The Department of Labor got 28,000 offenders placed through the program since we began.

Senator SPECTER. Who pays for the bond?

Secretary REICH. The Department of Labor. This has been going on, by the way, for 28 years.

TEENAGE PREGNANCY

Senator SPECTER. Mr. Secretary, I would like to see the specifics on that. I would like to see how many people it has been applied to, what the costs are, the payment of the bonds and what beneficial effect it has had. It has put the bonding companies in and they have an incentive to hold down their losses to get an accurate third party to try to help out the employees.

Let me move briefly to a second subject and that is teenage pregnancy prevention programs. I would like to put in the record, so it

will abbreviate some discussion here, a letter I wrote to you January 28 this year and your reply of March 18, 1994. I have quite a number of questions which I will submit to you for the record.

But touching on it just briefly now, this ties into what Senator Harkin has talked about welfare reform, it ties into economies, it ties into crime, it has been identified and I think accurately so by Senator Moynihan as the leading problem in the country today, unwanted pregnancies with emphasis on unwanted teenage pregnancies.

Senator Harkin and I sat down with Secretary Shalala and Secretary Riley last year and have given a lot of thought and Senator Moynihan has given a lot of thought to this subject. We are a fair distance I think from answers on it. This was the second part of the 3 a.m. amendment latched on where \$100 million were added for this program. So we can add funds that we can target to demonstration projects to see what happens.

So I think it is an overlap really with the Departments of Education, Health and Human Services, and Labor which comprise the jurisdiction of your subcommittee, and the costs are just astounding. I put this in the record last night when I was asked that that portion of my floor statement be incorporated at the conclusion of our questions and answers because I think it is relevant.

Something like close to \$30 billion a year in costs of aid to families with dependent children, WIC and other matters were very substantial. Perhaps as much as one-half of the cost of the deferred pregnancies were delayed. This is another matter which I think our staff is going to work on since we are going to keep this \$100 million no matter what happens in the full Appropriations Committee to get to some really effective use of targeting programs and following through saying what the results are. I would be interested now in your general view of the subject.

Secretary REICH. Senator, there is encouraging news and also discouraging news. The encouraging news is that there is a direct correlation between higher levels of training, higher levels of education, and lower levels of unwanted teenage pregnancies. We have reason to believe that school-to-work programs of the sort that we are initiating will help increase the skill level overall, thereby providing young people with more of a sense of their own futures, connecting school-to-work so that they can see that there is a future for them. In many of our schools young people don't see any connection between what they do in the classroom and the world of work and career, and that is how a lot of these young people get into trouble.

Here is my cautionary note. The summer training and education program which the Department of Labor undertook added remedial education and life skills components to traditional summer jobs. We found no difference in subsequent teen pregnancy rates between enrollees who received life skills training having to do with basically avoiding unwanted pregnancy and those who do not receive that training.

I raise that as a cautionary note because I think it in a way underscores my other cautionary point that very short-term assistance with severely disadvantaged populations, young people, particularly out of school young people, have not had a significant im-

pact in the job training area or even in the area of avoiding unwanted pregnancy. We must look at this more systematically. I am working with Secretary Riley and Secretary Shalala right now, but we have also got to provide them with longer term training incentives to stay in school, and then make sure that the summer program is integrated to do a year round school and work program.

Senator SPECTER. Secretary Shalala said that many of these teenage pregnancies occur at 3 p.m. to 7 p.m. in the afternoon. We have heard in the subcommittee proposals from private administration of the public schools. In one of the groups there was testimony by Schmidt. The President of Yale has a program that keeps children in school from 7 a.m. to 7 p.m., not all on academic training. What do you think of that as an effective means of dealing with the issue?

Secretary REICH. I simply don't know enough about it. It is interesting and I would like to explore it and I am sure Secretary Riley would like to explore it as well. I don't know any data which would shed light on whether that works or does not work.

Senator SPECTER. Well, 2 days ago we asked Secretary Riley to monitor it and report back to us and we look forward to that.

JOB SAFETY

My final question, Mr. Secretary, relates to job safety on OSHA and mine safety, both major problems. I would be interested in your overview as to what more can be done on both those lines.

Secretary REICH. On mine safety, we still have a way to go. The record is fairly good on a relative basis. That is, we have got what was several years ago a very unfortunate situation in terms of mine injury and also deaths. We have got that fairly under control. We have a number of regulatory proposals and we are moving very aggressively. Mr. McAteer is going to be testifying right after I am, and he will brief you on the specifics of some of those proposals. Our enforcement efforts in that area have picked up substantially, and we also are seeking some additional funding.

With regard to OSHA, there is encouraging but also discouraging news. The encouraging news is that fatalities are declining at the workplace. The discouraging news is that illnesses and injuries continue to increase particularly in areas like repeated stress syndromes. As we move from the factory to the office tower, what we are seeing is that more and more Americans are being exposed to different kinds of illnesses and injuries.

More and more American workers have to sit behind computers, for example, and carpal tendon stress is becoming a frequent problem. We are also hearing more and more from Public Health officials about problems of ambient air quality in offices with regard to tobacco smoke and other particles in the air, and we do intend to do something about that.

I want to bring to your attention, Senator, that we are seeking additional funding for our enforcement activities in OSHA and mine safety. For mine safety we are seeking \$2.8 million and 43 additional full-time equivalent people. We are pushing responsibility downward. This is the point I was making perhaps before you got here. Our attention is to reduce administrative and overhead costs and to push responsibility downward to the inspectors, both

for inspecting but also for prevention. One thing that we have found very, very successful in many of these areas, particularly in mine safety and OSHA, is to work with employers to avoid accidents before they occur. Many employers don't want to see those rising workers' compensation bills.

Senator SPECTER. There was one interesting program to have safety committees with the employees having greater participation.

Final question. Are you enjoying your job?

Secretary REICH. I am enjoying the job a great deal. Thank you for asking, sir.

But I did want to address the safety committees. In the OSHA reform legislation now pending there is a provision for worker/management safety committees. We have data that they do work as you suggest. The State of Washington and the State of Oregon have those kinds of committees. Not only has it not been a burden on business, in fact a lot of businesses say that it is extremely good because it has put a damper on the increase in worker's compensation claims and illnesses and injury problems. After all who is it who best knows where there are likely to be illness and injury problems better than the frontline worker.

Senator SPECTER. Thank you very much, Mr. Secretary.

Secretary REICH. Thank you, Senator.

Senator HARKIN. Senator Kohl.

OSHA REFORM

Senator KOHL. Thank you very much, Mr. Chairman.

Mr. Secretary, just to follow up on OSHA in general if you had to list your two or three major priorities on OSHA reform, how would you describe it?

Secretary REICH. I would say the OSHA reform legislation is the first priority in the OSHA area because, as I said, we have got to move from a commanded control system to a system that emphasizes prevention and gets the frontline employees actively engaged in preventing illnesses and injuries before they occur. I know of no better way to do it. The data we have out there shows that this kind of approach actually works and it is good for business. It brings down those worker's compensation costs.

Second, a major effort is underway with regard to ergonomics. We are talking about repeat stress syndromes where workers, often they are working in offices, are finding that because the way the work is configured, they are using small muscles over and over and over again. Tendons and muscles get very, very injured. These are serious problems. People are finding they have to miss work for periods of time because of this, and we are working on rulemaking with regard to this.

Then finally we intend to initiate rulemaking, and we are seeking clearance on rulemaking, with regard to ambient air quality and tobacco smoke in the workplace.

ADMINISTERING WELFARE REFORM

Senator KOHL. Mr. Secretary, what do you say to people who argue that the Federal Government has not demonstrated nor is likely to demonstrate an ability to handle welfare reform success-

fully. That welfare is far, far different, for example, than Social Security, which is basically a payment of money out to people and then our responsibility ends? That welfare reform is so complicated and so different from place to place in our country in determining where it has worked successfully that the best way for us to handle welfare reform would be to turn the moneys that the Federal Government is now spending over to the States and ask each State to submit a plan, that would need to be approved at the Federal level and then reapproved annually? That the work of welfare reform—getting people off of welfare and into good jobs—and can be best and most economically effected at the State level. What is your response?

Secretary REICH. That is very often the case, Senator, but not always the case. States have obviously different amounts of resources, different capacities. I think we want to have broad waiver authority in the welfare reform legislation allowing States to experiment. We want to give the states as much latitude as possible to be creative. There are a number of ways of getting people into work, providing job service assistance with information, and new ways of working with employers. I have seen around the country a lot of interesting experiments that seem to work in which employers are actively engaged in the process of training workers with some government help. I would say let's provide broad waiver authority, but let's not throw the baby out with the bath water.

There are certain broad goals that we have in common. There are certain frames of reference and there are limits to how the Federal taxpayer's money ought to be placed. I think that all Federal taxpayers in this country are owed accountability with regard to how fast people get on welfare and into work and also how those programs are generally constructive. So the short answer is, yes, let's give the States as much leeway as possible for creativity, but let's also make sure there is accountability at the Federal level to the taxpayer.

HEALTH CARE REFORM PROPOSAL

Senator KOHL. All right. In health care reform, Mr. Secretary, you must be surprised that business in general and small business in particular seems to be as opposed as they are to many parts of your health care reform plan. I know initially the administration made a big effort to elicit the support of business across the range of size and you in particular argued, as has the President, that small business should appreciate in fact what health care reform will do for them as it is proposed by the administration, that it is a good thing economically as well as socially and not something to be feared and opposed. Yet as you know, some business groups and particularly small business groups are strongly opposed.

Has the administration failed to communicate or do they know something that we don't know or is it political? Why are you not able to achieve a stronger degree of support from small business for your health care reform proposal?

Secretary REICH. Well, Senator, as you know, and I testified to this recently, small business is not a model. Small business does not march in lock step. In fact, one of the unique strengths of America's small business is that they are varied with regard to

their responses. Some of the national lobbying organizations located here in Washington regarding small businesses may come out in one direction but I can tell you there are enormous numbers of small businesses.

I encountered at the White House just a couple of days ago when small businesses got together in support of the President's plan, a lot of small businesses who like this plan. They understand that they are paying 35 percent more for the health insurance than they are paying for it in the large businesses, and they want to get the bargaining power that a purchasing cooperative would provide them.

They also want to get the subsidy. Right now they don't have any Federal offset. This gives them a subsidy. If they have relative workers, they are not going to take more than 3½ percent of their payroll.

Further, small businesses that do not now provide health insurance, and most small businesses do, generally want to provide it. They know that the best way to get good workers is to offer them good health insurance and, therefore, they want to be competitive in terms of other small businesses. As I have traveled around the country, I have done a lot of work with a lot of small businesses, and I have found very solid support for this program in the small business community.

Senator KOHL. So you are saying that they are for the most part on board, those that provide health insurance as well as those who do not provide health insurance, they all recognize for the most part that what you are offering is in their best interest economically as well as socially?

Secretary REICH. I have not seen a poll. I am saying that the national small business organizations here in Washington which have tended to oppose the President's plan do not speak for all small businesses. I believe on the basis of what I have seen and the people that I have talked with that there is a substantial portion of the small business community which is in favor of the President's plan and which include the mandate.

Senator KOHL. I would say in my experience, and I think it is probably true of most Senators that we get enormous opposition from small business and small business representatives to the mandate, to the requirement that all employers have to provide health insurance to their employees. These groups have enormous opposition to that and you are saying they are not really representative of their constituents?

I think it would be very helpful for everybody for us to try and determine that quantitatively. I think polls might do that. You are saying that you have not seen polls but your guess is that the opinion out there is not nearly as large against mandates as what we are being led to believe.

Secretary REICH. Also, and I want to go back to a point you made in asking the question, there is a lot of misinformation out there. Small businesses I talk with who get the information that understand what the President is proposing find themselves in much more agreement than small businesses not getting that kind of information.

Senator KOHL. And if that might be the case, the single largest problem that they don't understand is what you are offering and what positive impact there is going to be on that. And because the mandate may be the single biggest problem that we have in trying to pass health care reform, it would be worth almost any cost for us to get that information out if in fact it is misinformation that is guiding the opposition for the most part. No cost would be too much for us to engage in getting the information out because there is an enormous opposition out there to the administration's plan at the business level.

I will ask you another question on that. Do you think that a good share of that opposition is just simply political?

Secretary REICH. You are a much better judge of what is politics and what is not politics, Senator. My judgment is that certainly some of it is political. I think the business groups, particularly some of the business groups in Washington, seemed to be much more cooperative and much more willing to work with the administration on health care until the past month or so and then there was a distinct cooling. The plan didn't change—something else changed.

JOB CORPS SITES

Senator KOHL. OK. On the Job Corps sites you requested \$14.9 million for six new sites this year. Can you give us some indication as to what kind of cost we are looking at to complete those Job Corps sites?

Secretary REICH. Getting a Job Corps site up and running is going to cost around \$15 million per site and then the operation cost thereafter is about \$10 million a year.

Senator KOHL. Per site?

Secretary REICH. Per site.

Senator KOHL. About \$15 million per site to get it up and running.

Secretary REICH. And then the operational cost to keep it ranges about \$10 million a year.

Senator KOHL. All right. Well, as you know, Milwaukee was one of those cities that was hoping to get sited and I guess you are going to pick several more sites in the next year or two.

Secretary Reich. Yes; next year six more, the year after that six more.

Senator KOHL. Can you tell us, so that we can be successful, what your criteria are?

Secretary REICH. Because I have learned the ways of this town, I want to keep my hands absolutely off the selection process and leave it to the experts to whom I have allocated this responsibility.

Criteria No. 1, is the community in favor with what it is going to do.

No. 2, how did these Job Corps sites take advantage of facilities that are already there, military facilities or other facilities.

No. 3, what is the size of the poverty population in the area.

No. 4, how many Job Corps sites are in the region.

No. 5, what other Job Corps-like activities and programs are there to supplement and complement or even take the place of the Job Corps.

We apply these criteria as carefully as we possibly can. I was gratified, Senator, that there was as much interest in establishing Job Corps centers this year as was expressed by Congress. They tell me that not too many years ago there was not as much interest. A lot of citizens just didn't want Job Corps centers. I think it is a testament to how good this program is and how powerful the results of this program are that I have not encountered that problem at all. In fact, the reverse. People are eager to get the program; they know that this kind of program works.

Senator KOHL. All right. I thank you very much.

I thank you, Mr. Chairman.

SMOKING BAN

Senator HARKIN. Thank you very much, Senator Kohl.

Just a couple of followups, Mr. Secretary. Senator Kohl mentioned something about smoking. The State of Maryland recently ruled that on-the-job smoking should absolutely be a legal hazard according to hazards and safety laws. Barring a court challenge a total ban of smoking in all workplaces will take effect in May of this year.

Do you agree that smoking should be prohibited in all workplaces and does OSHA have the regulatory authority to ban smoking in the workplace?

Secretary REICH. OSHA has regulatory authority. We are seeking clearance for a proposed rulemaking. Again I am not willing to express my views at this point because this is a proposed rulemaking. OSHA is seeking clearance for proposed rulemaking on smoking and ambient air quality problems at the workplace.

CHILD LABOR

Senator HARKIN. Last, Mr. Secretary, I have been working for several years on a proposal to cut down and I have been for several years looking at different ways in which we can take a lead in the world community in stopping the last vestige, I think, of slavery in the world, and that is the use of child labor. Obviously we can't enforce other countries' activities in this regard. We have good offices that we can talk with them and try to bring them along but the scourge of child labor in this world is increasing rather than decreasing. In the Asian subcontinent and parts of Africa and indeed, I am sad to say, in our neighbor to the south, Mexico, children as young as 7 to 10 years of age working 12 hours a day 6 days a week, are both denied their childhood and denied the opportunity for an education and a better life.

So for the last few years I have been trying to figure out a way that we might take the lead in this. It occurred to me a couple of years ago that one of the ways to do that would be to prohibit the import into this country of articles made in whole or in part by child labor.

We don't know what the articles are. Polls taken in the country have shown that if an American consumer knows that an article is made by child labor and is imported and it is on the same shelf as an article that is not made by child labor and that is somewhat more expensive, that person will not buy the article that is made

by child labor. However, consumers don't know which article was made by a child. No one really knows.

So I think if we gave the consumers that information and beyond that if we in this country took the steps to ban the importation of articles made by child labor—again we are not forcing our views, our attitudes, our beliefs. If you want to endorse child labor, that is your business. We don't think you should but we are just not going to buy those articles in this country. We are not going to let them come into this country. There is a big market here for those articles.

I would just say to Senator Kohl that I started on this aspect of it a little over a year ago and because of even the threat of legislation, manufacturers, for example, of rugs and carpets in India and Pakistan have already started changing some of the workplace habits. In fact, every industry has its own magazine and the rug industry is no different. There are importers of rugs in this country now that advertise that their rugs are not made with child labor. So they are getting ahead of the market on this. It has been widely publicized in India, Pakistan, Nepal, Thailand and of course in Latin America. Again market forces are working there. If there is a market there and your rugs are not made using child labor, we will get into that market. That is what they are advertising so just a mere threat has had some impact.

Last year I asked the Department of Labor through this committee, and I appropriated funds for it, to do a study which is due this July to identify any foreign industry and its host country that utilized child labor in the export of products used in industry in the United States. Could you report on the status of the study and could you also direct your staff to arrange an indepth meeting with me and my staff as soon as possible on this?

Secretary REICH. Yes, Mr. Chairman. The study is ongoing. The staff already has conducted over 500 interviews with individuals and contacted international organizations concerned about child labor issues, as well as conducted miniature searches, traveled abroad extensively, and collected data extensively within the budget provided for this. The study is expected to be completed by July 15, 1994. I would be very pleased to help arrange any meetings.

Senator HARKIN. I would like to have the meetings as soon as possible.

Secretary REICH. Sure.

Senator HARKIN. I appreciate it very much.

Mr. Secretary, again I have some other questions that we will submit for the record. You have been very generous with your time here and I appreciate it very much.

Again, as you know, I have the highest esteem for you and I feel very strongly on those programs. You are trying to initiate the changes you are trying to make in the Department of Labor. I think even broader in the context of what we are trying to do in terms of the labor force or work force in America, in welfare reforms, you have been the leader in those areas. I just encourage you to keep up your strong voice within the Cabinet and here on the Hill and keep pushing us in the direction in which you are going. I look forward to working with you in years to come on this.

Secretary REICH. Thank you, Mr. Chairman. I look forward to working with you.

Senator HARKIN. Thank you.

PREPARED STATEMENT OF COMMISSIONER KATHARINE ABRAHAM,
BUREAU OF LABOR STATISTICS

We have received a statement from Katharine Abraham, Commissioner of Labor Statistics which will be inserted into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF KATHARINE G. ABRAHAM, COMMISSIONER OF LABOR
STATISTICS, BUREAU OF LABOR STATISTICS

Mr. Chairman and members of the subcommittee, I appreciate this opportunity to submit testimony to discuss the budget requested by the Bureau of Labor Statistics (BLS) for 1995. Our request would provide the BLS with the funds necessary to continue core programs that are of vital concern to the Congress, the policy making and program agencies of the Executive Branch, and the public, and also would support increased activity in four areas. The increases associated with our request are partially offset by program decreases, the largest of which are associated with the Administration's efforts to streamline governmental operations.

The 1995 request of \$367,106,000 represents a net increase of \$24,078,000 over the level appropriated for 1994, including the recent supplemental appropriation and associated budget rescission. Of this increase, \$17,195,000 is requested for improvements in our statistical programs.

The most important of the requested BLS program increases is the \$5,182,000 to support the revision of the Consumer Price Index (CPI). The Consumer Price Index is the Nation's most widely used measure of inflation. In order to maintain the accuracy of the CPI, the BLS historically has undertaken a comprehensive updating of the Index approximately every 10 years. One purpose of a revision is to update the market basket of goods and services that is priced. In addition, the revision provides the opportunity to change the areas in which prices are collected to reflect changes in the geographic distribution of the population and to incorporate improvements in survey technology and methods.

The goal of the CPI Revision is to produce an index that more accurately reflects economic conditions. The importance of this goal is underscored by the widespread use of the CPI for economic analysis, policy formulation, and contract escalation. The CPI also has a significant impact on Federal expenditures because it is used to adjust personal income tax brackets and exemptions as well as payments to social security recipients, federal and military retirees, and funding for entitlement programs such as food stamps and school lunches. For these reasons, the Vice President's National Performance Review strongly supported the BLS plan to initiate the CPI Revision in 1995.

The BLS also is requesting \$4,977,000 to fully fund the work done by the States to process and tabulate business establishment employment and wage data from the Unemployment Insurance system. These data provide a virtual universe list of non-agricultural business establishments that is used as the sampling frame for all of the BLS employer surveys, and also are a major input to the Gross Domestic Product statistics prepared by the Department of Commerce. The requested increase will allow the BLS to restore the States' ability to ensure that the data produced are of the highest quality. The funding also will enable the BLS to develop enterprise statistics and to conduct longitudinal analyses of employment in business establishments, thereby shedding light on the job creation process and on business births and deaths.

A further \$1,000,000 is requested to support two regular supplements to the Current Population Survey, to be conducted each January and May, that would allow timely collection of data on emerging labor market policy issues. The new supplements will explore topics such as "contingent" work, permanent job loss or displacement, work schedules, and other important issues. This initiative will provide information to promote the Secretary's goal of first jobs, new jobs and better jobs.

Finally, the BLS is requesting \$6,036,000 for a new youth cohort in the National Longitudinal Surveys (NLS) program. Data from the new youth survey will provide a better understanding of the labor force activities and problems of youth, particularly Black and Hispanic youth, as they prepare to become the work force of the

21st century. No national longitudinal data capturing the labor market experiences of teenagers in the 1990's are presently available. The proposed funding will allow BLS to produce reports on key labor market policy issues and to publish a periodic compendium of NLS data and research results.

The budget includes an additional \$14,488,000 for mandatory cost increases, including federal pay raises, and increased costs of data collection by the States and the Census Bureau under contract with the BLS.

Offsetting these increases, the budget includes a program reduction of \$3,332,000 in the funding for the surveys to implement the Federal Employee Pay Comparability Act of 1990 (FEPCA). Using both new technology and a change in collection methods, we expect to be able to deliver locality pay estimates to the Pay Agent for approximately the same number of geographic areas as during 1994. However, reductions in this area will require significant restructuring of data collection in the program, which provides occupational pay estimates for 38 specific areas and for the rest of the United States. The BLS, in consultation with the Pay Agent, will redefine the program to accommodate the reductions.

The 1995 budget would reduce funding for the Employment Cost Index program by \$250,000. As directed by the Congress, the BLS will seek full reimbursement in 1995 for the costs of preparing the Aircraft Manufacturing Employment Cost Index from the private sector users of the index.

This budget also includes program decreases of \$5,040,000 to help fulfill the President's goals of reducing the size of the Federal workforce and streamlining governmental operations. The BLS will seek to accommodate these reductions by performing its work more efficiently, cutting programs only when no such efficiencies can be found.

In summary, the 1995 budget request enables the BLS to continue production of essential data series as well as to launch several critical data important efforts. In view of the wide spread use of our products, in both public and private sector decisionmaking, this budget reflects a commitment to maintain and wherever possible, to improve the BLS programs.

EMPLOYMENT AND TRAINING ADMINISTRATION

STATEMENT OF DOUGLAS ROSS, ASSISTANT SECRETARY

INTRODUCTION OF ASSOCIATES

Secretary REICH. I would like to introduce our panel of Department of Labor Assistant Secretaries.

Senator HARKIN. I would be delighted.

Secretary REICH. They are here. Let me just ask them to come forward and sit here.

Doug Ross who is the Assistant Secretary for the Employment and Training Administration.

Joe Dear, Assistant Secretary for the Occupational Safety and Health Administration.

Bernard Anderson who is the Assistant Secretary for the Employment Standards Administration.

Davitt McAteer who is the Assistant Secretary for the Mine Safety and Health Administration.

With that I am going to take my leave.

Senator HARKIN. Thank you very much, Mr. Secretary.

Again we welcome this panel of Assistant Secretaries central to the Labor Department's important issue of protecting American workers to the importance of this law to those guaranteeing minimum wage, overtime payments as well as workplace safety and health.

BUDGET REQUEST

I am pleased to see the President is proposing an important initiative that is over \$66.7 million to finance 355 new full-time positions. The Secretary has mentioned that in his testimony earlier.

To save time I request the witnesses to briefly summarize their testimony, it can be included in the hearing record. I will withhold any questions until we have heard from each member of the panel.

Secretary Ross, we will start with you.

SUMMARY STATEMENT OF ASSISTANT SECRETARY ROSS

Mr. ROSS. Thank you, Mr. Chairman.

Thank you for this opportunity to appear today and to present the 1995 budget for the Employment and Training Administration.

You have heard from the Secretary that there are requests for increases in dealing with dislocated workers, school-to-work, and a system of one-stop centers increasing our commitment to the disadvantaged. On another level I would ask the subcommittee to look at this not as a separate set of programs being advanced but as an effort from the point of view of an individual American who is either working, wants to work, or is coming out of school and looking

for a way to get into the work environment, instead of as something that fits together as a whole.

Our vision, if we can put these pieces together, is that any American ultimately could walk into a one-stop center in their community and quickly get information beyond what we have now about what is available. This would include information on jobs, employment careers and what things pay, what new expanding jobs require in the way of skills, people who can help them to use that information to make choices about where they want to go, and how they can take control of their career and take the next step.

If it turns out that to take the next step and find a decent next job or a first new job they need some new skills, to be able to access with a career counselor a list of those in the community who are providing that kind of education and training. This would include access to good consumer report type information on what percentage of people who enroll in this finish it, what percentage of those end up in jobs related to what they were trained for, what are the starting wages like, and where are they a year later. If it turns out for dislocated workers, some of them disadvantaged, that that training is longer than a traditional unemployment insurance check, but turns out to be a necessary part of getting to a next step, then there is a way to get the training allowance to keep going to finish it. Further, throughout your life you will have access to this set of tools whether you are an 11th grader trying to pick a school-to-work option or someone who is 55 who decided they need a next job or a place to go.

PREPARED STATEMENT

And whether these are separate programs somewhere in Washington or not does not really matter. To you as an individual they are there for you to use quite irrespective of all these different programs. That is our vision and we hope and believe that the budget we are presenting moves us significantly from some of this disjointed place we are toward that kind of holistic society.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Mr. Ross.

[The statement follows:]

STATEMENT OF DOUG ROSS

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to appear here today.

The fiscal year 1995 budget for the Employment and Training Administration reflects President Clinton's commitment to put people first, to invest in our nation's greatest asset—American workers. The central charge to the Employment and Training Administration in fulfilling this commitment is to ensure that all Americans have access to the resources they need to successfully manage their job lives, and also to ensure that U.S. businesses are able to find the skilled workers and training resources they require to compete in a rapidly changing global economy. The American work force of today is vastly different from the work force our parents were part of, and the work force of the future is one for which our children will have to be educated and trained. Today's workers feel the effects of the changing economy as they see their earning power erode and their job security vanish, and they feel a growing need to adapt to the changes. At the same time millions of our citizens have never been part of the workforce or do not have the skills necessary to move up the economic ladder. The nation that grew rich with a workforce that had only an eighth grade level of literacy and little training now needs a different and better comprehensive system for producing a nation of workers with the skills that are

now needed. And the nation that defined job security as keeping the job one has needs to improve its ability to help its workers quickly and efficiently to the next—and better—job. The labor market programs that this country has had in place over the past 40 years have served their purpose well. But they do not constitute a comprehensive system.

The challenge to this nation, and to ETA, in creating a comprehensive system is enormous. To begin with, the system will have to:

- Help non-college bound students leaving school and entering the workforce to acquire the academic, technical, and general work skills required to begin immediately careers in firms that compete on quality.
- Establish voluntary national standards that define the skill levels and work competencies workers need to compete, or high-wage, high-skill jobs.
- Provide dislocated workers with easy access to a comprehensive system that provides them with job information and services, including the skill training on which high-paying jobs in the new skilled economy now depend.
- Provide adults who have never had a good job, or any job at all, with access to the quality education and training resources they need to escape intermittent employment at wages that cannot support a family well above the poverty line.
- Create an improved labor market information system. People looking for rewarding work need the best estimates of what good paying jobs are going to be available in the future, and where they can acquire the best education and training to acquire the skills for those jobs.

With these requirements in mind, the United States must rebuild its existing human resource development system, much of which was put in place before World War II. The worker investment and legislative agenda of the Clinton administration has been designed to create such a remodeled system. This new national—not federal—system for developing the skills of the U.S. workforce will be a partnership of local, State and regional entities, and the private sector will have a role no less important than the public sector. The Department's role, through ETA, will be to facilitate or broker the participation of all these players around a common vision of world class U.S. labor markets.

The Administration's fiscal 1995 budget for the Employment and Training Administration is \$10 billion for discretionary programs, nearly \$1 billion above the 1994 appropriations. We strongly believe this large investment is one that is based on a sound strategy for rebuilding our workforce development systems. It is cost efficient in the long run by reducing long term unemployment, reducing welfare costs, increasing government revenues, but most importantly, by providing all Americans more opportunities to compete in a high-wage, high-skill economy. The Administration's investments in workers include: a new and greatly expanded dislocated worker adjustment assistance program; a partnership with the Department of Education on a school-to-work transition system; a one-stop career center system; and a major expansion of Job Corps centers. In addition, the budget includes a major increase to the JTPA Adult Training Grants program and continuation of an expanded and enriched Summer Youth Employment and Training Program. Also included in the budget are funds for profiling unemployed workers—that is, early identification of long-term unemployed workers for referral to providers of re-employment services. Finally, funds are included to support the National Skills Standards Board.

These investments touch the lives of many of our citizens who need our help the most to gain entry into the emerging high-skill, high-wage workforce. Given the national deficit, difficult choices had to be made in allocating our investment funds. We believe we have invested in those programs that have been proven to be effective and in workforce systems we know will be effective and efficient. In making investments in programs that work, we also reduced funding in programs that have not proven effective. Funding for some programs of lesser priority was also reduced. Let me discuss each of the major efforts:

The budget for assisting dislocated workers proposes an investment increase of \$347 million in 1995 above currently appropriated levels. A total of \$1.465 billion is requested to assist dislocated workers. As we did last year, this funding is being requested under the current EDWAA authority. The Administration has proposed a new, enhanced and comprehensive program serving all dislocated workers, regardless of cause of dislocation, which we hope will be enacted this year, and begin implementing in program year 1995. The Re-Employment Act of 1994 will consolidate and replace the existing JTPA Title III dislocated worker program and five other programs serving dislocated workers. Dislocated workers will be assured of one-stop access to a broad array of employment and training services intended to help them find new jobs quickly or train for new careers.

A total of \$250 million is proposed in 1995 to continue establishing one-stop career centers, a second major component of the Re-Employment Act. These resources,

along with future years' resources, will act as seed money for States to establish one-stop career center networks and comprehensive labor market information systems. These centers will provide a common point of access to the full range of employment and training and related services available locally. One-stop career centers will make it easier for individuals to obtain improved local labor market information and referrals to job and training-related services. One-stop shopping also will provide enhanced job skills assessment and career guidance services to a wide range of clients to help them make informed career development choices in an ever changing economy.

Under the School-to-Work Opportunities initiative, funds will be used jointly by the Departments of Labor and Education over several years to develop the capacity of States, organizations, and employer associations to design and implement a national system for school-to-work transition. For 1995, \$300 million is requested in total for this proposal, divided evenly between the two departments. Resources will be spent under a joint plan designed and administered by these agencies. These funds will be requested under the new School-to-Work Opportunities Act currently pending in Congress.

The President's investment strategy in new jobs for young Americans includes \$1.2 billion for the Job Corps, including \$100.5 million to continue the expansion from 112 to 162 centers, with slots increasing from 42,500 to 62,500. The additional funds finance the completion of eight centers authorized by Congress in 1993 and 1994, one center from previous expansion efforts, and the first year's funding of six additional centers.

A total of \$1.056 billion is requested for Summer Youth Employment and Training. The amount includes \$184.8 million in addition to amounts currently available for the summer of calendar year 1995, and \$871.5 million for the summer of calendar year 1996. This level of funding will finance approximately the same number of participants as is expected for the 1994 summer program: 623,000.

An investment of \$9 million will be made in the Unemployment Insurance program to complete the establishment of automated profiling systems in States. The purpose is to identify those workers, early in the claims process, who are most likely to be long-term unemployed and to refer them to providers of re-employment services and training. This initiative will result in improve services and employment prospects for dislocated workers.

The President's budget request include \$1.1 billion for assisting disadvantaged adults participating in the Job Training Partnership Act Adult Training Grants program. This increase of \$142 million over the 1994 appropriation adds resources to a program of proven effectiveness that reaches the hardest to serve.

Other changes to employment and training programs include: An increase of \$14.4 million for Employment Service Allotments to States; Increases for the labor Market Information and Capacity Building activities which will support the investments in workforce development programs; An increase of \$12.4 million to support the activities of the National Skills Standards Board; A decrease of \$7.5 million for the Homeless Job Training demonstration program under the Stewart B. McKinney Act (authorization expires in 1994); A decrease of \$60 million to the JTPA Youth Training Grants program. Research suggests this program does not increase the employment and earnings of youth; and A decrease of \$9.9 million for the Targeted Jobs Tax Credit program.

Five million dollars is requested for the first quarter of fiscal year 1995, as the program expires on December 31, 1994, and no extension of the program is proposed at this time.

ETA's Program Administration account contains an increase of \$5.6 million above the 1994 appropriation level and a decrease of 22 full-time equivalent positions below the 1994 FTE ceiling. The request includes an increase of \$500,000 for staff development and training to build the skills of ETA staff in order to provide high-quality services to ETA's customers.

This concludes my statement, Mr. Chairman. I will be glad to answer any questions you or members of the Subcommittee may have.

BIOGRAPHICAL SKETCH OF DOUG ROSS

Doug Ross was confirmed as Assistant Secretary of Labor for Employment and Training by the U.S. Senate in August 1993. In addition to the traditional job and training programs, ETA is spearheading major Clinton Administration initiatives to promote workforce skill development.

Before joining the U.S. Labor Department, Mr. Ross was director of the Michigan Department of Commerce and was a visiting lecturer at the Institute for Public Pol-

icy Studies at the University of Michigan. He also served as a Michigan State Senator (1978-82) and as a Legislative Aide to Senator Joseph Tydings of Maryland (1968-70) and to Congressman John Dingell of Michigan (1963 and 1965).

Mr. Ross has extensive private sector experience in food brokerage and audio systems businesses. Mr. Ross was President of Michigan Future Inc., a non-partisan venture to create and promote long-term economic development and economic and human development. His writings include published works on government and reinvention as well as Robert F. Kennedy: Apostle of Change, published by Trident Press (1968).

In 1989 Mr. Ross was selected "Michiganiaan of the Year" by the Detroit News; in 1988 he received the National Governors Association Award for Public Service Excellence.

Mr. Ross holds a Masters in Public Administration from the Woodrow Wilson School, Princeton University and a B.A. in History from the University of Michigan.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
STATEMENT OF JOSEPH A. DEAR, ASSISTANT SECRETARY

BUDGET REQUEST

Senator HARKIN. Secretary Dear. This is the way I have you listed here.

Mr. DEAR. Thank you, Mr. Chairman.

I am Joe Dear. I am Assistant Secretary for Occupational Safety and Health.

OSHA's mission is to save lives, prevent injury and protect the health of American workers. Safe and healthy work places are productive workplaces, and they are profitable workplaces.

Our request for fiscal 1995 is for \$320,903,000 and 2,378 people to carry out that mission. This represents an increase of \$23.7 million from our fiscal 1994 appropriation and an additional 61 people to help OSHA to carry on its mission.

This request breaks into two parts. The first major program increase is the Department's enforcement initiative. We want to add \$15 million and 91 FTE's as our share of the Department's overall enforcement initiative. This has three components.

The first is to strengthen OSHA's inspection enforcement activity to add frontline safety and health compliance officers to conduct more inspections of hazardous workplaces in America. We want to use information technology to maximize the productivity of those inspectors, and to improve the information access within the Department and to the public. Finally we want to increase funding for our State plan partners. A great deal of OSHA's mission is conducted by the State plan partners.

The second part of our enforcement initiative includes increasing safety and health training opportunities. We want to add 13 new training grants for nonprofit organizations, to assist employers and workers to come into compliance and receive benefits of a safe and healthy workplace. We want to increase the number of education centers that are authorized to deliver training developed by OSHA's Training Institute.

There is a huge unmet demand by employers and workers to learn more about how to develop safe and healthy workplaces. We want to increase the numbers of centers and local educational institutions that can offer that.

Finally, under our enforcement initiative, we want to enhance our standards promulgation activity. We need to address the serious hazards that confront workers and employers. We want to do that expeditiously. We need additional resources to conduct the necessary technical and economic analyses to support that activity.

The second major request for funding is to allow us to improve our targeting. Our resources are tiny compared to the number of workplaces and the number of hazards that we are expected to reg-

ulate. If we can't target effectively, we waste the scarce resources we presently have. We have a request in our budget to allow us to develop a system using site specific data, so that we can get to the workplaces with the most serious threats to worker health and safety and conduct appropriate operations there.

These increases will allow us to direct standards and enforcement activity to the workplaces and the hazards which most seriously threaten the safety and health of American workers. This will enable us, along with our reinvention activities, to streamline our inspection process, to conduct more inspections, to get more standards out, to increase our capacity to pursue corporate wide settlement agreements and to conduct other innovative activities to enable us to do a better job.

We will be listening to our customers in terms of how they expect us to do our work and where they think we can improve. We need to increase our efforts with respect to whistle blower protection. We want to work with employers who conduct the safest and healthiest operations and expand their participation in our voluntary protection programs. This will enable them to accelerate the successful practices that they are engaged in throughout their industries, and enable them to show the way toward safer and healthier workplaces.

PREPARED STATEMENT

There is an enormous amount of preventable injury, illness and death in America's workplaces. This budget request will allow increases in enforcement, standard setting, education and training, and voluntary compliance activities so that we can help America's employers and workers make workplaces as safe and healthy as possible.

I appreciate the opportunity to make this presentation to you today.

Senator HARKIN. Thank you very much, Mr. Dear.

[The statement follows:]

STATEMENT OF JOSEPH A. DEAR

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to discuss the Occupational Safety and Health Administration's fiscal year 1995 appropriation request. The fiscal year 1995 budget requests a total of \$320,903,000 and 2,378 FTE—a net increase of \$23,659,000 and 61 FTE from 1994. This reflects a significant increase in the Department's commitment to enforcing the safety and health laws, as well as OSHA's share of the government-wide reductions intended to streamline government and reduce administrative expenses.

Secretary Reich and I are committed to building a revitalized OSHA, rededicated to its mission of saving lives, preventing serious injuries and protecting the health and safety of America's workers. In keeping with these vital goals, we are requesting a program increase of \$15,455,000 and 91 FTE to support OSHA's portion of the Department's enforcement initiative. Three major areas are covered by this initiative. First, the request will enable OSHA to strengthen its inspection enforcement activity in several ways, including: adding frontline compliance officers and investigators; focusing on those employers who fail to comply with safety and health regulations, including pursuit of litigation where appropriate; making maximum use of information technology to increase the productivity of our compliance officers and improve overall enforcement efforts; and increasing funding for OSHA's State plan partners to improve the effectiveness of their inspection programs. Second, the request will enable OSHA to increase safety and health training opportunities. Proposed activities in this area include: increased funding for an additional 13 training and education grants to the private sector, including indirect funding from a pro-

posed language change to utilize private sector tuition money at the Training Institute for these grants; and an increase in local education centers providing safety and health training sanctioned by OSHA. Third, the initiative includes enhancements for the standards promulgation activity, which will enable the agency to adhere to its new regulatory prioritization schedule, respond to emerging issues, and support increased standards development and regulatory studies.

The request also contains an increase of \$3,270,000 and four FTE to support an improvement in data available to OSHA. This increase will provide the initial resources for a comprehensive data collection system that will enable the agency to focus on employers, worksites and work practices that pose the highest risk of occupational injury and illness. This system will include establishment-specific data from the OSHA logs that employers are already required to maintain. Establishment profiles will be developed for targeting purposes.

The requested increases, combined with our reinvention efforts, will enable us to implement improvements in many areas. Inspections and standard setting will be directed to the most serious hazards. We are in the process of revising the Field Operations Manual in order to streamline the inspection and citation process to remove barriers to prompt and efficient enforcement. We are also looking at ways to streamline the lengthy standards development process. While strong enforcement and effective standards come first, we will also develop new and innovative ways to encourage cooperation between workers and employers, and educate workers and employers to create the safest and healthiest workplaces possible.

In fiscal year 1995 we plan to increase the number of onsite inspections and also expand other non-inspection enforcement activities. Overall, we anticipate approximately 42,900 Federal enforcement inspections in 1995. State safety and health inspectors in plan states are expected to conduct an additional 67,100 worksite inspections. Effective enforcement will include increased use of the egregious policy, and streamlining of this policy in consultation with the Solicitor of Labor. We will make increased use of criminal penalties where appropriate. OSHA will continue to focus on the deterrent effect of individual inspections by pursuing corporate-wide settlement agreements, which extend abatement requirements over entire multi-worksite corporations. The agency anticipates approximately 30 of these agreements in 1995. Enforcement efforts will be targeted where they will do the most good. This will include expanded use of pilot projects which use workers' compensation data to target the most hazardous workplaces in a state.

In previous years, OSHA relied primarily on the number of inspections conducted to measure its effectiveness. While the onsite inspection program continues to be an important component of the enforcement program, we are now looking at ways to measure the full range of agency intervention efforts. Programs designed to encourage employer voluntary compliance will be given added weight. The agency's customer service improvement plan will inform employees of opportunities to file complaints and obtain quick abatement in situations that may not require an onsite inspection.

State plans will promulgate and enforce new safety and health standards, and strengthen their enforcement and litigation strategies, in keeping with changes in the Federal program. The agency's State plan monitoring system will be fully operational, improving the evaluation of state programs.

OSHA's technical support staff continues to provide laboratory services, engineering expertise and regulatory analyses to support all aspects of the program. In 1995 we will implement an Information Technology Plan designed to enhance the technological environment in which the agency operates. This plan will coordinate the agency's data venues into a single information source to better serve the agency and the public. The agency's medical support staff will address many new and complex issues facing the health care industry. The development of a proposed ergonomics standard in 1994 should significantly increase requests for ergonomics analysis, as well as requests for information concerning ergonomics issues.

Designated state agencies will conduct approximately 26,250 onsite consultation visits to small employers under programs funded largely by OSHA. States will be encouraged to increase participation in the Safety and Health Achievement Recognition Program, which recognizes small worksites that have established effective safety and health programs. Areas of emphasis in the consultation program are expected to include confined space entry, process safety management, tuberculosis exposure, and bloodborne pathogens. The agency expects that the number of worksites participating in Voluntary Protection Programs, which recognize exemplary safety and health management programs, will continue to grow.

OSHA will continue to administer and maintain the national injury and illness recordkeeping system, providing guidance to both the public and private sectors. The final regulation for recordkeeping will be promulgated in 1995, and training of

OSHA personnel, state plan personnel, and the public will begin. Consistent with government-wide reinvention efforts, OSHA will experiment with new approaches to improve agency performance. These will include customer service improvement efforts, such as establishing a single source for standards and policy interpretations that customers can use, and decreasing backlogs for 11(c) discrimination complaints and VPP applications.

In keeping with our goal of strengthening OSHA, Secretary Reich and I are supporting rapid legislative action to reform the Occupational Safety and Health Act. OSHA has been effective in saving lives, as demonstrated by the steady decline in fatality rates over the past twenty years. Despite this and many other achievements, work-related injuries, illnesses and fatalities continue to inflict tremendous pain and suffering, and impose substantial economic costs on society. Most of these tragedies could be prevented with effective worker-management involvement. We urge the Congress to strengthen the tools which the agency now has to empower employers and employees to reduce or eliminate hazards from their workplaces.

Thank you, Mr. Chairman. This concludes my statement. I will be pleased to respond to any questions.

BIOGRAPHICAL SKETCH OF JOSEPH A. DEAR

Joseph A. Dear was confirmed as Assistant Secretary of Labor for Occupational Safety and Health by the United States Senate on November 8, 1993. As head of the Occupational Safety and Health Administration, Mr. Dear is responsible for administering and enforcing the basic provisions of the Occupational Safety and Health Act of 1970.

Prior to his nomination as Assistant Secretary, Mr. Dear served as director of the Department of Labor and Industries in Washington State from July 1987 until early 1993. He was appointed to this post after having served as deputy director from January 1985 until July 1987. In his position as director, Mr. Dear was responsible for both workplace safety and health, and workers' compensation programs. With the help of labor and management, Mr. Dear spearheaded a major reform of the workers' compensation program, converting a \$225 million deficit into a \$350 million surplus while stabilizing premiums for employers and improving benefits to workers. He also started health care cost containment and quality assurance programs.

Mr. Dear was president of the National Association of Governmental Labor Officials (NAGLO) in 1999-91. He served on the board of directors for the Occupational Safety and Health State Plan Association (OSHSPA) from 1989-93. Mr. Dear also served as chairman of the State of Washington Investment Board, which manages public pension portfolios and workers' compensation funds totaling more than \$19 billion.

Before joining the state government, Mr. Dear was research director of the Washington State Labor Council from 1981-85. He was the founder of People for Fair Taxes, a public interest coalition of labor, church and civic organizations supporting progressive state and local tax policy, and served as the organization's executive director from 1977-81.

Mr. Dear graduated from The Evergreen State College in Olympia in 1976, with a bachelor of arts degree in political economy. He is a 1986 graduate of Harvard University's program for Senior Executives in State and Local Government. Mr. Dear is married and has two children.

MINE SAFETY AND HEALTH ADMINISTRATION

STATEMENT OF DAVITT McATEER, ASSISTANT SECRETARY

BUDGET REQUEST

Senator HARKIN. We next turn to Assistant Secretary McAteer, Mine Safety and Health Administration.

Mr. McATEER. Mr. Chairman, thank you very much for this opportunity to appear before this committee today. It is appropriate that we have the hearing today because March, this month, is the 25th anniversary of the passage of the 1969 Coal Mine Health and Safety Act which is the hallmark or the landmark safety and health law particularly as it applies to mines in this country. The purpose of that act was to protect the Nation's most valuable resource, the miner. We have made great strides in the past toward achieving that purpose.

We are at a point in our time now when we think that we might be able with the current funding to go further in achieving that purpose so that we might arrive at a day when a person can enter a mine and not have to fear the loss of limb or life, and not have to sacrifice part of their health to be employed as a miner and to exit that working life at retirement age a full and healthy person. We think that the budget that we are proposing of \$203,185,000 for 2,548 FTE will go a long way toward achieving that purpose.

That budget will cover our mandated activities including the four inspections for underground mines and the two inspections for surface mines, and also will allow us to embark upon a number of initiatives where we can address particular problems that have occurred and where we can attempt to make inroads in those problems.

Among the initiatives that we propose is work with the small mines. Small mines historically have had a notorious health and safety problem. Their records indicate that they have an accident rate five times that of some of the larger mines. We would like to target those mines and to put emphasis in those mines both in the enforcement side as well as in the education and training side.

One of the initiatives we are proposing in this budget is to do just that. To begin this initiative we are proposing a small mine summit in the next several weeks in which we are bringing in the mine operators to accompany the associations, the union officials, as well as miners themselves and their families, to attempt to embark on a joint campaign to see what steps we can take to attack those particular problems.

Second, in the area of health we are proposing an initiative as well, and we are asking for an increase in funding. Health in the mines has been a neglected area. It has not had the emphasis placed upon it that we think necessary, and we would like to

change that. We would like to address some of the health concerns that have not been addressed up until this time.

Those include repetitive motion injuries that occur in the mines, coal dust, other respirable dust, and noise as well as other health matters. We propose again to bring our own people together at the present time to address where we are now with miner's health and what we might do about taking steps to increase and improve health for miners both in underground and surface mines, both in the coal as well as metal and nonmetal mines in this country.

Third, we are looking at an initiative to try and put technology in the hands of our inspectors. What we are simply saying is that we believe that our frontline inspectors can do a much better job if they have computer technology and computer ability. When they go to the mine, they can have access to the mine plan, to the accident and the violation record of the mine, and they can use these computers to get prompt information to address that particular mine's problem. We believe that this will help not only with the enforcement but also with the direction of our education and training to address the problems at that particular mine.

PREPARED STATEMENT

We think that these three initiatives will allow us to address the miners' particular problems so that at the end of the day we can improve the chances that a miner can come out of the mines and not have to sacrifice his health, not have to sacrifice safety, and that the miners' families can rest more assured that the miner will come home without injury or illness.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Secretary McAteer.

[The statement follows:]

STATEMENT OF J. DAVITT MCATEER

Mr. Chairman and members of the subcommittee, I am pleased to appear before you to discuss the fiscal year 1995 appropriation request for the Mine Safety and Health Administration (MSHA). It is fitting that this hearing is this month, because March is the 16th anniversary of the effective date of the Federal Mine Safety and Health Act of 1977 (Mine Act). The Mine Act, which MSHA is charged with enforcing, is a landmark among the world's safety and health laws. The budget we are proposing is built on the foundation of this law, and the lessons learned from the past. It is our aim with this budget to move forward, and to address the compelling needs that still remain in the mining industry.

The budget now before you requests \$203,186,000 and 2,548 FTE to conduct mine safety and health activities. It provides resources to perform all mandated inspections and other activities required by the Mine Act and to support several new initiatives in the enforcement area. The request represents an increase of \$8,184,000 and 6 FTE from 1994 and consists of a program increase of 43 FTE and \$4,258,000 for the new enforcement initiatives and net mandatory cost increases of \$6,851,000 offset by program decreases of 37 FTE and \$2,925,000. The decreases are spread among all program activities and reflect streamlining plans now under development. The request complies with the President's directives to reduce administrative costs and federal employment, and it finances most of the enforcement initiatives within MSHA's existing FTE ceiling.

MSHA's mission is to protect the safety and health of the Nation's miners. Accomplishing that mission calls for an aggressive, broad-based, enforcement policy; an enforcement policy which holds all of those who have authority over a mining operation responsible for compliance with the laws designed to protect miners' safety and health.

MSHA is committed to fulfilling its statutory mandate. The Agency will continue to conduct inspections, to address miner's complaints of unsafe conditions or unfair

or discriminatory treatment, to investigate hazards, and to provide technical and educational assistance to the mining community. These activities must be driven by one overriding objective: making the Nation's mines, large and small, less dangerous places to work. The successful enforcement of the Mine Act will be measured by a continuing decline in preventable harm to miners. To shape the future, MSHA will learn from the past. Better use of the detailed accident data available to the Agency will be a primary Agency goal in 1995. MSHA's long-term role must be to ensure that compliance with the Mine Act becomes integral to the culture of the mining industry, as well as uniform across the industry. Mine owners and operators who abide by the Act should not find themselves at a competitive disadvantage.

MSHA's recent winter-alert campaign is a model of what the Agency can and should do. Experts have long recognized that deadly mine explosions caused by methane and coal dust are more common in the winter. During its campaign, MSHA supplied more than 200 public service announcements to radio stations, broadcast a mine-safety alert video by satellite, and sent more than 1,000 inspectors, supervisors, and specialists to conduct spot checks for critical safety violations and to talk directly to mine operators and miners. Bringing that information home to the mining community, coupled with a strong enforcement presence, will save lives.

Other threats to miners' health must be fought day-in and day-out. Coal miners are exposed to respirable dust that destroys their health with grim predictability. Dust exposure has been regulated by statute for 25 years, but MSHA's dust-enforcement program has been plagued with admitted tampering on the part of some operators and widespread difficulties in achieving compliance with the dust standards. These problems continue to put miners at terrible risk of contracting a disease which should be a thing of the past. Efforts to detect, punish, and deter dust level violations will become an increased priority for MSHA. MSHA must take broad action to insure not only the integrity of the dust-sampling process, but also its effectiveness. The goal of the Mine Act is to insure that a life spent working in the mines is not a slowly-executed sentence of death. MSHA intends to be able to determine, with accuracy and confidence, the quality of the air miners now breathe on the job and its effect on their health. The Agency intends to focus on the long neglected area of miners' health. New regulatory initiatives will be needed. As a first step, the Agency will convene a conference examining current perspectives on miners' health issues and the outlook for the future.

MSHA will combine a renewed dedication to basic enforcement concerns with reinventing the Agency's operations. MSHA has begun work toward implementation of a new procedure for handling contested civil penalty cases that involve small amounts of money, as opposed to major issues of law or policy. The Alternate Case Resolution Initiative aims to free attorneys in the Solicitor's office to focus on other, higher priority matters. Specially trained MSHA personnel will be authorized to represent the Secretary of Labor in about twenty percent of proceedings before the Federal Mine Safety and Health Review Commission.

In another area, MSHA will seek to extend its enforcement authority to a substantial portion of nonmetal mining operations that is now excluded from MSHA's enforcement of training regulations by restrictive appropriation language. It is time for all miners to benefit from the Mine Act's training provisions. While many of the exempt operators do provide safety training for their employees, many do not. MSHA needs enforcement authority to address those operators who do not provide training to their employees. These miners should not have to suffer the higher injury rates experienced at exempt operations due to a lack of training.

What follows is a brief discussion of the 1995 budget proposal by program activity.

ENFORCEMENT

A total of \$153 million and 2,012 staff years is requested in the budget for enforcement activities at both coal and metal and nonmetal mines. This is an increase of \$7 million and 17 FTE from 1994. It includes increases of 25 FTE and \$1.6 million to address the safety problems at small coal mines and contractor-operated mines, 18 FTE and \$1.2 million to enforce new and revised health standards and \$1.4 million to equip enforcement personnel with laptop personal computers (PC's). Offsetting the increases are program decreases of 26 FTE and \$1.9 million.

Small mine safety.—Safety problems at small coal mines are notorious. Workers at mines with less than 10 workers have five times the risk of fatal injuries as those at mines with over 50 workers. In 1995, MSHA proposes new, more aggressive enforcement approaches to combat this problem. Historically, to meet the annual inspection requirements of the Mine Act, MSHA inspectors spend 3 to 10 consecutive days each quarter at a mine conducting an inspection. This has allowed some small operators to cover up problems in one area while the inspector is inspecting another

area, and, upon completion of the quarterly inspection, some operators can ignore safety standards for several months before the next inspection.

MSHA's new small mines program would modify the typical inspection pattern of one inspection each quarter for a few consecutive days. Instead, teams of 2 to 5 inspectors would arrive unannounced and move quickly to a number of underground locations simultaneously, eliminating the ability to hide violations ahead of inspectors. Additionally, inspections would be broken up. The 3 to 10 consecutive days currently used would be spread over several weeks, cutting the lengthy period without federal inspector presence.

A contributing factor to the problem at many small mines is: the collapse of effective oversight and regulation of the persons who most directly influence safety conditions, supervisors and foremen. Prior initiatives have failed to address this root cause, but MSHA's new efforts in this area will be devoted to restoring accountability for mine safety. Enforcement must discourage mine owners and operators from delegating safety responsibility to persons unfit or unwilling to exercise it. In order to address this issue, MSHA intends to cite owners as well as operators and others who have actual authority for the operation of the mine and the safety and health of the miners. MSHA also plans to call a Small Mines Summit within the next sixty days. State regulators, educators, and industry, labor, and community representatives will be convened to address the training and certification of mine supervisors and foremen. MSHA will propose that certification become a federal responsibility.

Smoking in the mines—the cause of 29 needless accidental deaths since the Mine Act was passed—must also be addressed by MSHA.

Health initiative.—In fiscal year 1995, as part of its health initiative, MSHA will enforce revised air quality standards and new hazard communication standards, both scheduled for promulgation as final rules in 1995. In addition to updating the permissible exposure limits for airborne contaminants, the revised air quality standards will include more comprehensive requirements on respiratory protection, carcinogen handling, and exposure monitoring. The new hazard communication standards will require mine operators to inform miners of the presence and nature of hazardous chemicals in the workplace.

New technology on the frontlines.—In order to increase our efficiency and effectiveness in fiscal year 1995, MSHA will purchase laptop PC's for frontline enforcement personnel. Whether on routine inspections or in criminal investigations of willful violators, MSHA's enforcement personnel need to know the corporate record, including accident history, in order to detect and act on evidence of violations with full knowledge of the surrounding circumstances.

Currently, inspectors make pen and pencil notes to record all aspects of their inspections and any conditions leading to citations. They have access to a mine's history in the office, but not with them during inspections. Once the inspector completes the inspection, appropriate forms are filled out, reviewed by the supervisor, typed, and entered into the existing information systems. With today's technology, laptop PC's can be programmed to complete forms, enter data directly into the current information systems, store mine file and inspection history information, and issue citations. The use of PC's will increase inspector productivity and provide immediate access at the mine site to useful accident, inspection and compliance data.

Communicating new direction.—The full commitment of MSHA's management and inspectorate team will be fundamental to our success in carrying out these enforcement initiatives. In the near future we will convene a meeting of key MSHA enforcement personnel to lay the foundation for working together, and achieving our objectives.

ASSESSMENTS

A total of \$3.9 million and 53 FTE is requested for the Assessments program in 1995. This is an increase of \$81,000 and a decrease of four FTE from 1994. Civil penalties encourage compliance and are an important enforcement tool. In both 1994 and 1995, we will move to more closely integrate the assessment and enforcement programs, focusing on the goal of accident prevention. The Assessments activity is expected to assess approximately 140,000 violations of the Mine Act per year and vigorously collect and account for all penalties paid.

EDUCATIONAL POLICY AND DEVELOPMENT

In fiscal year 1994 and 1995, Educational Policy and Development will be focused on providing support for the Agency enforcement efforts. Steps will be taken to more closely tie education and training activities to the Agency's enforcement program and to place more effort on prevention of accidents. Additionally, in order to strengthen and diversify the educational material provided by the MSHA Academy,

we will call together a group of academicians from the mining community to review our curriculum and provide input. A total of \$15.2 million and 84 FTE is requested for the program in 1995. This is an increase of \$642,000 and a decrease of one FTE from 1994. The National Mine Health and Safety Academy will provide 725 course days of instruction to MSHA personnel and the mining community.

TECHNICAL SUPPORT

A total of \$22 million and 275 FTE is requested for Technical Support activities in 1995. This is an increase of \$159,000 and a decrease of 5 FTE from 1994. The Technical Support activity will continue to provide direct support to MSHA's enforcement activities by making its technical expertise available to solve mining problems to further the health and safety of miners.

PROGRAM ADMINISTRATION

A total of \$8.8 million and 124 FTE is requested for Program Administration, a decrease of one FTE from 1994. The Program Administration activity will provide policy direction and administrative support for MSHA's safety and health programs.

CONCLUSION

Today we are reminded not only of the Mine Act which has been so instrumental in moving our nation forward in the effort to provide miners with a safe and healthy workplace, but we are also reminded of the terrible tragedy that lead to passage of the Act. March 9 marked the 18th anniversary of the Scotia mine disaster which claimed 26 lives. It is important that the legacy not be lost. We must be ever vigilant to improve the lives of miners today and tomorrow.

Mr. Chairman, that concludes my prepared statement. I appreciate this opportunity to appear before you and welcome any questions you have.

BIOGRAPHICAL SKETCH OF J. DAVITT MCAETER

J. Davitt McAteer was appointed Assistant Secretary for Mine Safety and Health on February 9, 1994. He has responsibility for carrying out enforcement, training and technical programs in administering the Mine Safety and Health Act to ensure that more than 300,000 miners work under safe, healthful conditions at the more than 14,500 mining operations.

Mr. McAteer had been serving as a consultant to the Secretary of Labor at the Mine Safety and Health Administration prior to his appointment. From 1984 to August 1993, he served as Executive Director of the Occupational Safety and Health Law Center and prior to this position, worked for the Mining Project of the Center for Law and Social Policy. He served as Solicitor of Safety for the United Mine Workers of America from 1972 to 1976, and before assuming that position, worked at the Center for the Study of Responsive Law.

Mr. McAteer produced and directed an award-winning video about the history of mine safety and health in the United States, and among his publications was the Miner's Manual, a comprehensive legal and practical guide for rank-and-file miners. A visiting lecturer at several universities, he has also served on a number of advisory and research bodies.

Mr. McAteer, a West Virginia native, is a graduate of Wheeling Jesuit College and the West Virginia University College of Law. His involvement with mine safety and health issues began in law school, when he developed and directed a study of the West Virginia coal industry.

EMPLOYMENT STANDARDS ADMINISTRATION

STATEMENT OF BERNARD E. ANDERSON, ASSISTANT SECRETARY

BUDGET REQUEST

Senator HARKIN. Next we will go to Secretary Anderson of the Employment Standards Administration.

Mr. ANDERSON. Good morning, Mr. Chairman. I am pleased and honored to appear before you today representing the Employment Standards Administration. I might add that this is my first appearance before the subcommittee, having been confirmed by the Senate for this position only 4 weeks ago today. I will make a very brief opening statement and I ask that my full statement be included in the record of the hearing.

The request for the Employment Standards Administration for fiscal year 1995 is \$285.9 million for full-time equivalent staff years of 3,756 and that represents an increase of \$18.2 million and 91 FTE over the level of appropriations for fiscal year 1994.

The major thrust for the effort in 1995 will be the Department's enforcement initiative. You have heard reference to that from the previous two speakers. I would just like to mention the four governing principles of the Department's enforcement initiative which are first of all to target the worst offenders and the worst actors, to protect the most vulnerable populations, to deter violations through significant penalties and to get results swiftly and efficiently.

One of the ways we intend to move forward the implementation of those principles is to reinvent the way we do business in the enforcement area. There will be a major restructuring effort underway to look at the way enforcement is conducted with a view toward largely putting more resources in the hands of the frontline workers, workers in the field. We are going to shift resources from supervision to frontline investigation, to decentralize much of the decisionmaking, to empower frontline workers to do their job better and most importantly to provide modern technology in the form of upgraded data processing systems and equipment so that people in the field who are engaged in the enforcement activity will be able to do their job much better and to do it faster.

Another part of the Department's overall enforcement initiative is the request for 105 term FTE to expand the periodic roll management project from the four district offices in which it has been applied over the past year to all 12 district offices. Thus far the project has achieved savings of about \$32 million through fiscal year 1993. If the savings that have already been achieved are extrapolated into the future and the project is enlarged from 4 district offices to 12, it is estimated that through fiscal year 1999 over \$300 million will be saved in workers' compensation costs.

Finally, there is an important need to increase the resources available to train employees. I have been advised that because of budgetary constraints within the Department over the past few years, the amount of funds available for training have been very limited. There is a request in our budget for \$1 million for training which will facilitate the enforcement initiative and will provide training in a variety of areas to improve the quality of the work that is done by the staff in the field, particularly those engaged in enforcement activity.

I would think, Mr. Chairman, that the type of emphasis that I would like to place on this is to provide the kind of maximum protection for American workers through the application of the appropriate labor standards while at the same time bearing in mind the overall cost of providing such services. Funds are limited. Budgets are rarely as large as those who run the programs would like. At the same time I think there is an obligation on us all to use those funds as efficiently and effectively as possible to get the job done. I think that is possible given the system's changes and the kinds of initiatives that we plan to undertake in fiscal year 1995.

PREPARED STATEMENT

I will end my statement there, Mr. Chairman. Thank you for inviting me. I would be delighted to answer any questions you might have at this time.

[The statement follows:]

STATEMENT OF BERNARD E. ANDERSON

Mr. Chairman and Members of the Subcommittee, this is my first appearance before the Subcommittee and I am pleased and honored to appear before you today as a representative of the Employment Standards Administration (ESA) of the Department of Labor to discuss ESA's fiscal year 1995 budget request. Let me begin by providing an overview of our agency's fiscal year 1995 request.

The Employment Standards Administration fiscal year 1995 budget request for Salaries and Expenses is \$285.9 million and 3,756 full-time equivalent (FTE) staff years. This represents a net increase of \$18.2 million and 91 FTE over the comparable fiscal year 1994 level.

Our primary goals during fiscal year 1995 will be to preserve the integrity and quality of our programs and strengthen the effectiveness of our enforcement and service delivery for the millions of people our programs serve. At the same time, we will work to reinvent and reengineer the way we do our work to achieve the most efficient use of our resources.

The Department has developed a three-pronged workforce investment strategy of first jobs, new jobs, and better jobs. As one of the components of the strategy for better jobs, the Department has established an enforcement initiative to better address its evolving law enforcement responsibilities. Enforcement initiatives have been developed that seek to target the worst actors and offenders, protect the most vulnerable populations, deter violations through the use of significant penalties, and get results more swiftly and efficiently. Major elements in reinventing and restructuring enforcement activities include expanding the use of modern information technology, putting computers into the hands of more frontline workers, more strategically targeting compliance and enforcement activities, and economizing scarce litigation resources by expanding the use of Alternate Dispute Resolution. Putting more of our human resources in frontline enforcement positions and providing additional travel funds to get these employees out conducting investigations are also integral parts of a restructured enforcement approach.

To support the Department's enforcement initiative and achieve our goals, ESA is requesting an additional 145 FTE and \$13.9 million specifically for new enforcement initiatives and \$1 million for training our frontline staff. ESA's enforcement request includes funding for an additional 40 FTE and increased enforcement travel and ADP funds. These funds will be used to mount coordinated enforcement efforts

targeted at low-wage industries where workers are most vulnerable, and the worst violations and violators of equal employment opportunity and wage and labor standards. The resources will facilitate reinvention initiatives including shifting staff resources from supervisory functions to frontline enforcement, decentralizing enforcement activities, empowering frontline enforcement staff, reengineering work processes, and providing frontline enforcement staff with modern technology and computer-based investigation support resources.

The funds requested for enforcement ADP will allow our investigators to put data obtained during investigations directly into our automated information systems; will provide them with immediate access to an establishment's compliance history and to investigative reference materials; and enable investigators to more promptly resolve investigations.

Also as part of the Department's overall enforcement initiative, 105 term FTE and related funding are requested to expand the Periodic Roll Management (PRM) Project in the Federal Employees' Compensation Program. The current project has already resulted in significant savings to the FEC Special Benefits Fund (over \$22 million through fiscal year 1993 with projected savings of over \$179 million through fiscal year 1999). Expansion of the PRM Project will result in an additional savings of \$131 million in workers' compensation costs through fiscal year 1999.

As part of an Agency training initiative, and to meet the Secretary's training investment goals, ESA's fiscal year 1995 request includes an increase of \$1 million for training our employees, especially our frontline employees. At the same time that new skills, ideas and techniques are required, tight fiscal constraints in recent years have curtailed ESA's ability to properly train its workforce. This situation has adversely affected ESA's ability to implement new responsibilities and more effective approaches to accomplishing its mission, as well as to improve professionalism, consistency, and productivity of each individual ESA program. The training funds requested will begin to meet frontline staff training needs that have been neglected for too long and which are necessary for successful reinvention.

The Special Benefits fund request for fiscal year 1995 is for \$2 billion, of which \$258 million is a direct appropriation to the Department of Labor. Reimbursements from other agencies are expected to total \$1.8 billion.

The fiscal year 1995 Black Lung Disability Trust Fund request is for an appropriation of \$995.5 million. This amount includes \$536 million for benefit payments, \$407 million for interest payments on advances, and \$52.5 million for administrative costs.

Let me briefly outline the fiscal year 1995 budget request for each of the ESA programs.

ENFORCEMENT OF WAGE AND HOUR STANDARDS

A total of \$102.8 million and 1,343 FTE is requested for the Wage and Hour Division to enable the program to carry out an expanded program of targeted investigations, more promptly investigate and resolve complaints, promote voluntary compliance by employers, address new responsibilities such as the Family and Medical Leave Act of 1993, carry out new enforcement initiatives aimed at serious violators, and reinvent its way of doing business.

Vigorous enforcement of the wide range of laws that establish standards for wages and working conditions, covering most private and public employment, will continue. Our major objective is to achieve compliance by employers through direct enforcement activities, including resolution of complaints, and by promoting voluntary compliance through enforcement and education and outreach.

The fiscal year 1995 request includes an increase of 23 FTE and \$3.5 million in support of the Department's enforcement initiative, including \$540,000 for enforcement travel and \$2.2 million for information systems development in support of improved enforcement. An additional \$356,000 is requested for training with the primary emphases being criminal case development skills and procedures, and work process reinvention.

Overall, we expect that approximately 65,000 compliance actions will be completed under the wage and labor standards mandates, including the Fair Labor Standards Act (FLSA), Government Contract labor standards statutes, the Migrant and Seasonal Agricultural Worker Protection Act, various provisions of the Immigration and Nationality Act (INA), the Employee Polygraph Protection Act of 1988, and the Family and Medical Leave Act of 1993.

FEDERAL CONTRACTOR EEO STANDARDS ENFORCEMENT

A total of \$59.9 million and 833 FTE is requested for the Office of Federal Contract Compliance Programs (OFCCP) to administer its directed enforcement programs and investigate and resolve complaints on a timely basis.

The fiscal year 1995 request includes an increase of 16 FTE and \$2.3 million in support of the Department's enforcement initiative, including \$460,000 for enforcement travel and \$1.3 million for information systems development in support of improved enforcement. An additional \$228,000 is requested for training that will focus on the development of frontline staff skills.

We will pursue our mission to assure equal employment opportunity by Federal contractors by enforcing the contractual obligations imposed by Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and 38 U.S.C. 4212 and the employment eligibility provisions of the Immigration and Nationality Act. OFCCP will continue to give special emphasis to the enforcement of EEO requirements in apprenticeship and training programs pursuant to 29 Part 30 of the National Apprenticeship Act and the elimination of the glass ceiling through Corporate Management reviews. OFCCP will continue to reinvent and streamline its enforcement processes to improve the quality of enforcement and increase job opportunities for minorities, women, individuals with disabilities, and covered veterans. As an agent of the Equal Employment Opportunity Commission, OFCCP will also enforce Title I of the Americans with Disabilities Act of 1990.

FEDERAL PROGRAMS FOR WORKERS' COMPENSATION

In ESA's workers' compensation programs, our fundamental responsibility is to ensure that the interests of injured workers, employers, and the Federal government are properly protected throughout all stages of the claims management process, including the adjudication and processing of claims for wage replacement compensation, medical, and other benefits provided by the Acts. Promptly processing incoming and pending workloads while maintaining a high degree of accuracy, fiscal integrity, and quality customer service remain the goals of the program.

Federal Employees' Compensation Act

A total of \$73.1 million and 1,040 FTE is requested to administer the Federal Employees' Compensation Act (FECA) program to assure timely and fair payment of compensation, continue improvements to avoid interruption of income to injured employees, and bring about earlier return-to-work and rehabilitation where appropriate.

This request seeks additional funding of \$8.1 million and 105 four-year term staff to support the expansion of the Periodic Roll Management (PRM) Project as recommended by the National Performance Review. The current four office project is expected to produce \$179 million in workers' compensation benefit cost savings through fiscal year 1999 at an administrative cost of \$12.7 million. Another \$131 million in benefit savings could be expected through fiscal year 1999 if additional PRM teams were established in the remaining eight district offices. The administrative costs for these additional teams would be \$29.2 million for their full four-year term appointments.

FECA's request for training is \$236,000, which will provide staff with skills and case management training to ensure earlier medical intervention, better claims management, and earlier return to work for injured workers.

The Assisted Reemployment Project that began in fiscal year 1992 will continue in fiscal year 1995. Under this project, compensation funds are used to pay employers some of the cost they incur when they hire injured Federal workers. As of December 31, 1993, 147 injured workers were in the program and 102 of these placed in new jobs. Cumulative savings to the compensation fund attributable to the project totalled over \$663,000 through fiscal year 1993. Savings projected for fiscal year 1994 are \$531,000 and for fiscal year 1995 more than \$1 million.

Longshore and Harbor Workers' Compensation Act Program

A total of \$9.8 million and 127 FTE is requested for the Longshore and Harbor Workers' Compensation Program to maintain the accuracy and timeliness of claims processing activities and achieve a high level of service to the program's customers. We will continue to emphasize efforts to sustain quality claims processing and adjudication services, conduct a comprehensive technical assistance program for employers, insurance carriers, and covered employees, and monitor the Special Fund. An additional \$85,000 for training is requested as is an additional \$203,000, to be generated through fees levied against insurance carriers and self-insurers, to provide for necessary oversight and maintenance of the Longshore Special Fund.

Black Lung Program

Resources requested for the Black Lung Program are for \$28.4 million and 284 FTE needed to effectively manage the program's caseload. Included in this request is an additional \$70,000 to provide informal conference training to District Directors, Senior Claims Examiners, and selected journey-level claims examiners. The Black Lung Program will maintain prompt adjudication of claims, effective management of its debt portfolio, and efforts to achieve the highest possible level of accuracy in income maintenance and medical care benefit payments.

PROGRAM DIRECTION AND SUPPORT

A total of \$12 million and 129 FTE is requested to provide administrative support to the agency's service delivery programs in the areas of information resources management, productivity and quality improvement, Departmental goals and objectives, and support services functions. Four basic strategies for providing leadership on ESA's quality improvement efforts will be emphasized: (1) promoting broad employee involvement in identifying and exploiting opportunities for reengineering and reinvention to effect operational improvements; (2) broadening the use of new technology to improve delivery of services; (3) re-engineering and simplifying work processes and requirements while improving the quality of agency products and services; and (4) simplifying the organizational structure, where appropriate. ESA's enforcement request includes one FTE and \$50,000 for PDS to provide essential assistance in implementing ESA's ADP enforcement initiative. The request also includes an additional \$25,000 for staff training.

CONCLUSION

Mr. Chairman, this concludes my formal statement. I thank you for the opportunity to present our budget request and outline some of our initiatives to the Subcommittee. I want to reaffirm our commitment to using our resources to effectively protect the interests of American workers while keeping the costs of the delivery of these needed services as low as possible. My staff and I will be pleased to answer any questions that you or the members of the Subcommittee may have.

BIOGRAPHICAL SKETCH OF BERNARD E. ANDERSON

Bernard E. Anderson was confirmed by the Senate on February 28, 1994, as Assistant Secretary for the Employment Standards Administration, comprised of the Wage and Hour Division, the Office of Federal Contract Compliance Programs, and the Office of Workers' Compensation Programs.

Prior to his appointment, Mr. Anderson was president of The Anderson Group, a Philadelphia, Pennsylvania, economic and management advisory firm which provides strategic planning information for private and non-profit organizations. He was formerly a tenured full professor at the University of Pennsylvania's Wharton School of Finance and Commerce; a lecturer in economics at Swarthmore College in Swarthmore, Pennsylvania; the Director of the Social Sciences Division of the Rockefeller Foundation, and a Visiting Fellow in Public and International Affairs, Woodrow Wilson School, at Princeton University. Mr. Anderson has authored five books and numerous articles on economic and employment policy. He began his career as an economist for the U.S. Department of Labor, Bureau of Labor Statistics.

He has served on many public service boards addressing employment and economic development issues, and between 1991 and 1994, he served as chairman of the Pennsylvania Intergovernmental Cooperation Authority, the fiscal oversight board for the City of Philadelphia. Prior to his appointment to the Federal service, his memberships on professional and corporate boards included the Manpower Demonstration and Research Corporation for which he was Vice Chairman, the Provident Mutual Life Insurance Company, and Lincoln University, for which he was Chairman of the board of trustees. He is a member of the American Economic Association, former executive board member of the Industrial Relations Research Association, and former president of the National Economic Association.

Mr. Anderson received a Bachelor of Arts degree in economics graduating with highest honors from Livingstone College, Salisbury, North Carolina; a Masters of Arts in Economics from Michigan State University, East Lansing, Michigan; and Ph.D. in Business and Applied Economics from the University of Pennsylvania. He also received an honorary L.H.D. from Shaw University.

FEDERAL EMPLOYEES' COMPENSATION FRAUD PROVISIONS

Senator HARKIN. Thank you very much, Secretary Anderson.

We will start with you. In the fiscal year 1994 appropriation bill I personally put in a provision which bars workers' compensation benefits to individuals convicted of a crime in the program. We found that that was going on, that they had been part of the program and they are still getting worker's compensation. The Inspector General's Office has recommended expansion of this provision which would suspend benefit payments to incarcerated and convicted felons.

Tell me about that. Would you support such a legislative charge? Maybe we could do this in the appropriations process. Do you have any idea how many individuals would lose benefits under the administration of this, what the cost of this might be? If you ever have that information out, would you provide it for the record?

Mr. ANDERSON. First, Mr. Chairman, let me say that we do support the amendments that have been proposed. The staff from the Office of Workers' Compensation programs participated with the Inspector General's Office in preparing the analysis of fraud in the FECA system that led to the National Performance Review recommendations incorporated in the proposed legislation. So we support the amendments and we hope that they will be enacted.

I don't have data on the number of persons who might have had their payment suspended because of incarceration. I believe the number is relatively small but I can provide that information for you for the record.

Senator HARKIN. I would appreciate that.

[The information follows:]

FECA FRAUD PROVISION IMPACT

The National Performance Review recommendations have been incorporated in H.R. 3400. The NPR proposal would amend the Federal Employees' Compensation Act to (1) make fraud against the program a felony, (2) suspend benefits to incarcerated felons, and (3) extinguish the right to further FECA benefits for persons convicted of FECA fraud. The 1994 ESA appropriation implemented the third item, effective October 21, 1993.

Since October 1993, ten FECA claimants have been convicted of FECA fraud. An additional ten cases are estimated for the remainder of fiscal year 1994, yielding a total savings of \$400,000 for the year. Enactment of the provision regarding incarcerated felons would, after taking account of reduced payments that would still be made to dependents, suspend benefits to 13 felons and save another \$190,000 per year. Enactment of the increased penalty for FECA fraud may have some impact on the number of convictions achieved, as it may increase the likelihood of prosecutorial interest.

MINIMUM WAGE AND OVERTIME LAWS

Senator HARKIN. I have some concerns about enforcing minimum wage and overtime laws. Now you have requested 23 additional staff to strengthen the force of minimum wage staff that you have offset by a reduction of 20 staff in compliance with government line reductions in employment.

How many more wage/hour compliance officers do you have in fiscal 1995 compared to fiscal 1992? And again, if you don't have that, you can supply it.

Mr. ANDERSON. We do have those numbers. At the present time the authorized level is 822 investigators. I think as of mid-Feb-

ruary there were 791 and efforts are under way now to increase hiring to bring it up to the 822 number for fiscal 1994.

The request for the budget in fiscal 1995 will raise that number to 846 investigators, and every effort will be made to reach that number if the budget is approved. Let me say that in addition to bringing on board new people through the restructuring there will be a shift of staff from supervisory to frontline positions which then will also provide for people involved in the enforcement effort in the field. So these two mechanisms are being used now to increase the amount of enforcement involved in the Fair Labor Standards Act.

Senator HARKIN. What can you do about employers who fail to keep records, fail to execute wage and hour violations, no record of recordkeeping violations?

Mr. ANDERSON. At the present time my understanding is that employers who are charged by employees as having violated wage and hour standards, and have not paid their wages or work employees overtime inappropriately, are subject to an investigation in which both current and former employees are interviewed so that the degree of nonpayment can be revealed. This takes place during the investigation. The employer then will be obligated to make such payments.

Now in the adjudication of such cases I believe that as a result of Supreme Court rulings the weight of evidence is strongly on the part of the employee in that the employer has a very heavy burden to demonstrate that allegations on the part of the employees, that they have not been properly paid, will have to be refuted by some reasonable evidence presented by the employers, and thus in many cases, employers who have not kept the appropriate records would not be able to provide the information.

Senator HARKIN. That is a lengthy court process. I wonder if you would be in favor of an amendment to the law to allow imposing stiff fines for not imposing standards?

Mr. ANDERSON. Discussions of possible recommendations to amend the Fair Labor Standards Act are now underway and the possibility of asking for a civil money penalty for recordkeeping violations will be considered.

SMALL MINE INITIATIVE

Senator HARKIN. Secretary McAteer, can you tell us how much more this issue will cost over the length of the program?

Mr. MCATEER. Mr. Chairman, let me refer to my notes so that I am accurate. We have allocated 25 FTE for our small mine initiative in the coal area. We believe that that number will assist us in bringing about an improvement in this area that has been so hard for us to make progress in. These additional moneys will be part of the overall \$4.3 million program increase that we are requesting.

INCREASE FOR OSHA'S TARGETING SYSTEM

Senator HARKIN. Let me turn now to OSHA, Mr. Dear. Your budget includes an increase of \$3.270 million to support the initial phase of the multiyear budget to improve OSHA's targeting inspec-

tion on employees. Can you tell us how much this effort will cost when it is fully implemented?

Mr. DEAR. Our estimate is that when it is implemented it will be about \$8 million a year.

Senator HARKIN. Why can't you use the worksite specific data that the Bureau of Labor Statistics already collects? It costs some \$17 million per year if we have to pay for it.

Mr. DEAR. I have been working with Commissioner Abraham at the Bureau of Labor Statistics on a report pursuant to an Appropriations Committee request, dealing comprehensively with the issue of how OSHA can use the data for targeting and evaluation purposes. The Bureau of Labor Statistics feels it is extremely important to protect the confidentiality of their data, and that is an extremely important consideration.

At the same time, OSHA cannot function if it does not have sites indicated for targeting. We have learned that the survey size of BLS's sample of employers, particularly for manufacturing, is not large enough to sustain the targeting system required by OSHA.

So the main issue is not confidentiality, but OSHA's ability to obtain information necessary to build a targeting system. That is why our proposal uses as a foundation the OSHA 200 log, which employers currently maintain. We will be able to collect that information comprehensively and use it as a foundation for targeting.

Senator HARKIN. Well, wouldn't the information you would get from the Bureau of Labor Statistics—I understand their desire for privacy and the fact that they might not get accurate information if they didn't keep it private—but could you not use at least some of that information that might not divulge specific site information but to use their overall information as a way of better targeting \$8 million a year that you are going to have to use?

Mr. DEAR. Absolutely. I am anxiously awaiting the product of the safety and health system which BLS will begin to report very soon, potentially as soon as next month and certainly by May. They are going to tell us a lot about the causes and consequences of workplace accidents and illnesses, and that will allow us to direct resources to selected industries for special emphasis and to greatly improve our resource allocation.

Nonetheless, in order to have an effective targeting system, we have got to have site specific data. The only effective national source of that is the OSHA 200 log. We will need resources to be able to collect that data and analyze it.

USE OF NIOSH DATA

Senator HARKIN. How about NIOSH? They always like data on all these things. What kind of working relationship do you have with NIOSH?

Mr. DEAR. Our relationship with NIOSH is getting better every day, every week. I am exceptionally fortunate in that the person I worked with in my home State of Washington, Dr. Linda Rosenstock, has just been employed as a Director of NIOSH. She and I cooperated when I was an agency Director in Washington State. We exchanged staff between OSHA and NIOSH. The same thing can be done to enhance our partnership under the Occupational Safety and Health Act. NIOSH can give us specific site infor-

mation, but nobody can give us the site data that tell us where the worst hazards are, so that we can target our efforts.

Senator HARKIN. That is what NIOSH does. I mean NIOSH should be able to give you that information.

Mr. DEAR. They can give us tremendous information about hazards, about scientific issues and how to address them, and it can be particularly helpful with respect to health care because we are not doing as much as we should. But there is no other place to go for site specific data. We need to know which construction site, we need to know which manufacturing facility to target, and the only place to get that is the OSHA log.

Senator HARKIN. Well, we are going to have to take a close look at that and I hope you work with our staff to avoid duplication of effort and utilizing the best sources of information. As you have seen from the charts that we have here, we are under a pretty tight crunch and I just hope you can streamline. I want to be sure that we are using the most streamlined method.

Mr. DEAR. I would be pleased to work with you to accomplish that.

Senator HARKIN. I appreciate it.

Secretary Ross, this is something I have heard quite a bit about in Iowa. As you know, we are third in the Nation in terms of the portion of people over 65 in the population and we are No. 1 in the Nation in the number of people over 85.

You are asking for a reduction of \$14.44 million in community services employment for older Americans. That will mean 2,400 fewer job opportunities for low-income persons over age 65. It is a very popular program not only with seniors but the communities in libraries, nursing homes, schools, child care centers. In many cases, I don't think this an anecdote, many of the seniors who work in these programs, it's what gets them up in the morning, gets them going, gives them encouragement.

Many people have told me that perhaps without this their health would dwindle and they might even become more of a burden on society in terms of needing more care. So it has been helpful to the elderly, it has been helpful to a lot of these programs. The child care centers where they work, I have seen them work there. The relationship between them and the young kids is tremendous.

So that is going to mean quite a few cuts in these opportunities for people in my State and a lot of other States. So what should I tell them about this cut?

Mr. ROSS. The reason for our recommendation that we go back to the level of a program funded in fiscal 1993 is really twofold. First, of course, the overall budget constraints exist that you cited.

Second, because we are looking at expansion in two other areas that offer resources and opportunities to also help older Americans with employment possibilities, in some cases even more skills, because there are many people at 55 who still think they can learn a new thing or two. I can cite two specifics. First is the increase in title II-A for adults. We are asking for an increase of \$141 million there and all of those who are over 55 who have somewhat lower income would qualify for assistance there.

And the second is, as you know, we are asking for an increase of \$347 million for dislocated workers which include long-term un-

employed. Many of those over 55 are people who obviously worked all their lives and their job ended and they have been out of work; they would like to go back to work. This offers another opportunity for that group of Americans. So while we do move back \$14 million in terms of this appropriation, these other programs offer opportunities, and no one who is currently working should lose their job. This will not cut off anybody who you think is currently holding a job.

Senator HARKIN. The problem is, Secretary Ross, that many of these elderly get on Social Security. So you are talking about the dislocated worker program. If they go back to work, they lose their Social Security and on this program they don't. A lot of times many of these elderly that I have seen on this program, Social Security is their only means. They don't have a nest egg. They worked all their lives and they are basically at or right below the poverty level and this community service employment gets them at least off poverty. So I don't know that this dislocated work program is going to help them a great deal.

Mr. ROSS. It would vary with the individual. You are obviously going to have the appropriate program by going back to the 1992 levels and the margin reduces there. Some of them will want part-time jobs which you would get under title II-A and dislocated workers. Some of them will want new skills who are really not 55 and don't have Social Security yet. Our notion is by having these different resources to fit different needs we can ultimately serve more older Americans than we currently do. I could go back again and cite the fact that it depends on the individual, and since we are expanding in other areas this seemed to be an area where, without injuring anyone, we could come back with the previous year's funding.

Senator HARKIN. Well, you have an increase of \$141.979 million in the adult training program in title II-A and you are cutting \$14.44 million out of community service employment. Why don't we just take that money and restore it back in there and give these 2,400 people that would lose their jobs the assurance that we will be able to have a community service employment?

Mr. ROSS. I think first we believe that no one who currently has a job would have to lose it. We don't regard it as the case of having to RIF anyone. Second, the title II-A resources are really targeted for the disadvantaged, people who are not able at this point to support themselves very well. So it is a question of making sure the people who can't make ends meet have resources. To the extent an older American fits that, they get that priority too. But given the choice we are concerned here about people who don't have enough to put food on the table and make ends meet.

Senator HARKIN. Well, we are going to have to take a look at this. This one bothers me a great deal. Again if there is a better way to accomplish this, if there is a more streamlined way of doing it, I am not opposed to that. I know about this community worker program and title II-A, and again it is geared for something else. It is geared for basically full-time employment for workers who have been dislocated because of job shifts and that type of thing. It is not geared toward elderly who are on Social Security who need

a little part-time job. It is just not geared that way, it is not in focus at all.

Those are my concerns. If you can convince me that another way is the best way to go, fine, we will do it. Just be aware that the community services employment program has a lot of support here on the Republican side as well as the Democratic side. We have seen it work in communities and that there is a lot of support, so just be aware of that.

Mr. ROSS. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you all very much for being here. That concludes my questions. Thank you for being here.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

JOB CORPS EXPANSION

The FY 1995 budget requests funding to initiate six new Job Corps centers -- these centers would be in addition to those eight centers initiated in FY 1993 and FY 1994. I am concerned about the commitment that you are asking this Committee to make in the out years by starting another six centers. For example once these centers are completed, they have to have money to operate. The operations costs in the out years for the eight centers already in the pipeline will be about \$260 million per year. Another six centers will add another \$120 million or so to the cost of operations.

Question. Given the fact that we are facing a five year freeze in discretionary funding and that we could well be below a freeze over the next five years, how do you propose to pay for the operation of these centers in the out years?

Answer. First, I would like to correct the record concerning operating costs for the new centers. Once they are activated in 1996 and 1997, the operating costs for each of the 8 new centers that were initiated under the 1993 and 1994 appropriations will average less than \$10 million per year. The net operating expense for all 8 centers in 1997 is therefore estimated to be approximately \$77 million.

The additional 6 centers we are proposing to initiate in FY 1995 will also cost roughly \$10 million per center per year to operate upon activation in FY 1998. The annual operating cost for all 6 centers will be approximately \$60 million. The long-term Job Corps expansion being proposed by DoL will therefore exert much less pressure on the outyear budgets than suggested in your question.

Within the tight caps for discretionary spending, the President has made the long-term decision, starting in FY 1995, to make room for an annual expansion of Job Corps through cuts in other programs in the Federal budget. As in the FY 1995 budget request, difficult funding decisions will be faced in future budget submissions in which programs proven to be ineffective will be decreased or eliminated while programs with proven effectiveness will be maintained or increased. We believe that Job Corps will continue to demonstrate a high level of cost effectiveness and will be able to compete successfully for funds against other federal discretionary programs.

CUT IN THE JTPA TITLE II-C YOUTH TRAINING GRANT PROGRAM

Your prepared statement refers to a recent study which "confirmed mounting signals that conventional short-term training programs for disadvantaged youth fail to have any positive impact on their job prospects or earnings." As a result of that study, your budget pares back youth training funds by 9 percent.

(Background: The current appropriation of \$658,682,000 covers the program year July 1, 1994 through June 30, 1995; the proposed cutback to \$598,682,000 would not take effect until the program year beginning July 1, 1995.)

Question. If this program is such a waste of money, why is it only being cut 9 percent?

Answer. The National JTPA Study, which showed disappointing results for JTPA Title II-C out-of-school youth, covered the period 1987 to 1989 and only 16 of the 640 service delivery areas. We believe that substantial improvement in the quality and effectiveness of services has taken place since then. This most difficult to serve part of our population will not be helped by withdrawing assistance.

Based on the JTPA study findings, the Department is moving forward to strengthen Title II, especially youth programs. First, we think that the JTPA Reform Amendments of 1992 passed by Congress move the system in a positive direction, so we will vigorously implement them. Second, we have proposed legislation to authorize "Reinvented SDA Labs" in up to 75 sites where we will waive requirements which inhibit innovative program design. We will evaluate innovative designs or those that we know work in order to identify effective out-of-school models. Third, we will engage the JTPA system and local communities in a dialogue around what they regard as appropriate changes in Title II to make it work better. Fourth, we are expanding the replication of the successful CET model for serving out-of-school youth. Finally, we will continue to conduct research efforts to find better ways to serve out-of-school youth.

Question. Are you planning to reprogram this money at a later point into some new youth training activity?

Answer. No. The FY 1995 budget request seeks to invest a greater amount of funds in other youth training programs than that which was decreased from Title II-C. The Department has invested in new School-to-Work initiatives and youth programs of more proven effectiveness. Compared to the FY 1994 level, the 1995 request provides increases of \$100.0 million (+200.0%) for School-to-Work programs; \$168.0 million (+18.9%) for Summer Youth Employment and Training programs; and \$116.3 million (+11.3%) for Job Corps. The net investment in youth programs has increased by \$324 million for 1995. In the future, we will continue to fund the youth programs at levels consistent with the FY 1995 request and will adjust those levels as program evaluations identify what programs work best.

PAY/GO PROVISION FOR RE-EMPLOYMENT ACT INCOME SUPPORT PROVISION

One of the features of your proposed Re-Employment Act is to include income support payments as part of the discretionary program costs instead of continuing to pay for those benefits as a mandatory. Discretionary funding has been cut. As a matter of fact, we could be operating well below a freeze over the next five years.

Question. Why should we pay for a mandatory income support program out of scarce discretionary dollars -- why shouldn't the income support costs be paid for under the Pay/Go provisions of the Budget Enforcement Act?

Answer. The Re-Employment Act (REA) has a unique "mixed" program design, including a mandatory component and a discretionary component. When the program is fully implemented in FY 2000, extended income support for workers who have one year or more of tenure with their previous employers and are enrolled in training will be supported by capped mandatory funding through the Unemployment Insurance system. All other services will be paid for with discretionary funds.

During the period prior to FY 2000, a portion of the REA extended income support will be paid with discretionary funds because of budgetary constraints. During FY 1995 - FY 1999, extended income support for those workers with one to three years of tenure with their previous employers will be paid with discretionary funds. In order to make room for these discretionary income support payments, as well as significant increases in other discretionary funding under the REA, the President made tough decisions reducing funds in other Federal programs. He also clearly articulated his priorities in the FY 1995 budget request. The Administration's five-year budget also makes room within the budget caps to expand the program, making further cuts in other lower-priority programs in the outyears. Thus, the REA, which is budgeted within the tight spending caps, is a high Administration priority.

Prior to FY 2000, income support payments for workers with three years or more of tenure will be paid for with mandatory funds. The Administration proposal contains a total of \$2 billion for these mandatory costs. This amount will be capped in the legislation, ensuring that expenditures will not exceed this amount. These costs will be fully offset by reductions in other mandatory expenditures. In sum, this proposal is totally paid for -- both in the short and the long term.

The reason that the dislocated worker income support costs could not all be funded on the mandatory side during the transition period is due to the fact that the primary offset identified for the proposal -- the FUTA .2% surtax -- was extended until December 1998 as part of the 1994 Reconciliation bill; therefore, it is not available for purposes of Pay/Go until that date. However the President was able to identify cuts on the discretionary side that allowed income support costs to be financed on the discretionary side during this interim period.

The discretionary income support costs identified in the Department's estimates are simply estimates -- there is no set-aside in the law that requires a specific amount to be spent on income support. If the Appropriations Committee were to reduce the funding for dislocated workers by the amount estimated to be needed for discretionary income support (\$161 million in FY 1995), it would simply mean that 125,000 fewer people would be served.

If the bill were to be changed to eliminate the provisions related to discretionary income support, it would result in

inequitable treatment of dislocated workers and undermine the goal of the provision, which is to enable workers to participate in long-term training. If only workers with more than 3 years of tenure are eligible for income support, 35 percent of the dislocated worker population would be disqualified from receiving needed income support.

RE-EMPLOYMENT ACT INCOME SUPPORT PROVISION COSTS

Question. What is your estimate of the cost of these income support payments over the next four years?

Answer. The income support costs to be funded out of discretionary dollars during the first five years of the program, FY 1995 through FY 1999, will total an estimated \$818 million. By year the estimates are:

<u>Fiscal Year</u>	<u>Amount in Millions</u>
1995	\$161
1996	\$181
1997	\$202
1998	\$208
1999	\$66

These discretionary funds will provide extended UI payments to those program participants who have more than one year but less than three years of tenure with their previous employers and are in long-term training. During the same period, extended income support for those participants with three years or more of tenure will be paid for by capped mandatory funding through the UI system. Beginning in FY 2000, when the program is fully implemented, all income support costs will be shifted to the mandatory side so that all extended income support payments for participants in training will be paid out of capped mandatory funding.

Streamlining Government

Question. You've requested \$25 million for a reinvention Investment Fund and \$11.2 million for an "enforcement automation fund". What types of projects do you contemplate being funded with these resources?

Answer. The requested increases for both the Enforcement Automation initiative and Investment in Reinvention Fund provide the Department with two separate sources of funds that are necessary to further the Department's mission and foster our streamlining and reinvention goals. However, the two increases are for distinct and different purposes and therefore we think it would be helpful to explain each request and its potential benefits.

The first request covers the Investment in Reinvention Fund. It would provide a one-time \$25 million appropriation to capitalize the Fund initially. Agencies would borrow from the fund to finance certain projects and then be required to reimburse the Fund from savings that result once the project is implemented. Borrowed funds would be repaid with interest and by the end of the fiscal year

following the year in which the project is completed. The Fund is self sustaining after the initial appropriation. These funds would be available to all DOL agencies for any approved project that would generate sufficient future savings to repay the loan.

Often, annual appropriations do not provide sufficient flexibility, time or funding to allow an agency to undertake larger projects with potentially bigger payback. This Fund would give DOL a practical alternative to finance innovative projects that will produce improved operations and cost savings.

The second request is for \$11.2 million for enforcement automation. This request is in the Departmental Management account and is earmarked exclusively for enforcement-related, cross-cutting applications that have Department-wide or multi-agency implications. No-year funding is requested to allow time for the longer planning and coordination cycle associated with projects of this nature. Funding was requested in the Departmental Management account to provide the flexibility to finance projects that cut across agency lines. These funds are earmarked for enforcement-related projects and will not be used for administrative support functions. Our enforcement agency heads are actively involved and will make sure that funds will be allocated for intended purposes.

We have not made any decisions on individual projects to be financed from the Investment in Reinvention Fund. We will set up a task force, composed of representatives from all agencies, to develop selection criteria to determine which projects and proposals will be financed as well as the terms of repayment for loans made to agencies for reinvention projects. The group will also establish guidelines and controls that will govern the establishment as well as the ongoing maintenance of the Fund.

As for the enforcement automation request, the Secretary has already established a working group comprised of the heads of the agencies with enforcement programs to decide how this \$11.2 million will be used. The Director of our Information Resources Management organization is providing the necessary administrative and technical support to that working group. We anticipate that these funds will be used to finance enforcement-related projects that have DOL-wide or multi-agency applications, such as Alternative Dispute Resolution or possibly major communication systems, that will produce DOL-wide improvements enabling us to work more efficiently and effectively.

Both requests support the National Performance Review recommendations. The Investment in Reinvention Fund is based on the NPR recommendation to establish innovation funds. The enforcement initiative responds to an NPR recommendation that DOL do more to integrate its enforcement activities.

Question. Would projects include paperwork reduction and streamlining government activities?

Answer. They most definitely would. As I noted in my prepared opening statement, I am committed to improving the Department's programs through reinvention. I fully support the principles of the President's National Performance Review, and is actively seeking additional ways to streamline operations including reductions in supervisory levels and empowerment of front-line staff. Our goal is to operate more efficiently, economically and effectively within employment ceiling and budget constraints. In other words, to do more with less.

Both the \$25 million for the Reinvention Investment Fund and the \$11.2 million for enforcement automation are essential to that effort because they will provide us with the time, funding and flexibility to design, develop and undertake the kind of projects that will allow us to achieve the necessary economies and still improve on our accomplishments.

Please be assured that paperwork reduction is one of our major goals. Not only will we reduce internal paperwork, but also the paperwork we require from our customers. In FY 1993, we cut down on paperwork by eliminating 73 percent of the DOL Manual Series and simplifying the procurement and timekeeping systems. We have eliminated many internal reports and cut down the frequency of reporting in other cases. OSHA has reduced its operations manual by more than two-thirds. We expect to do much more with the funds we are requesting for FY 1995. For example, using these funds to provide our front-line employees with state-of-the-art technology and communications systems will reduce the need for hard copy reports and reference material. Extending Alternative Dispute Resolution techniques and use of bulletin boards should reduce paperwork as well.

REDUCTION IN ADMINISTRATIVE OVERHEAD EXPENSES

Question. What would be the impact, agency by agency, of a three percent across-the-board cut in administrative overhead expenses?

Answer. Over the past few years, the Department has been required to absorb the costs of several pay increases and other across-the-board cuts to meet overall budget constraints. For example, the DOL appropriation acts for FY 1992 and 1993 included general provisions for across-the-board cuts to meet spending caps. DOL is absorbing over \$25 million in locality pay costs in FY 1994 as well as a rescission of \$4.0 million. In addition, DOL's FTE levels were reduced by 181 in FY 1993, 271 in FY 1994 and 273 in FY 1995 to comply with the President's goal to reduce Federal employment, and the budget was reduced by a total of \$21.4 million in FY 1993-1994 for administrative cost reductions required by executive order. Further administrative cuts are already identified in FY 1996 through FY 1998. As might be expected, the Department decided to absorb a disproportionate share of these required reductions in administrative overhead areas. The Department has reached a point where it can no longer achieve significant savings in these areas.

It will be virtually impossible to absorb further reductions, no matter how small, without having an immediate impact on the FTE levels of support programs. That will lead to an adverse impact on direct program operations, either because necessary direct support services will be delayed or eliminated or those tasks will have to be performed by front-line staff at the expense of program activity.

A three percent across-the-board cut in administrative overhead expenses would have the following impact:

Employment and Training Administration:

A 3 percent reduction to ETA's Program Administration appropriation is approximately \$4,300,000. This reduction would lower the number of FTE in ETA by approximately 56, to a level of 1,591 FTE. The current FY 1994 ETA ceiling is 1,669 and the 1995 request is 1,647.

This reduction would have a major adverse impact, coming on top of a 22 FTE reduction and a 3 percent administrative cost reduction already built into the budget. This reduction includes 14 FTE that ETA plans to use to assume its leadership role in implementing the President's workforce development strategy, including the Re-employment Act, School-to-Work, and a major Job Corps expansion.

The reduction from the FY 1995 plan would result in delays in reviews, inspections, grant approvals and create backlogs in areas such as alien certification. The reduction would also severely restrict staff training, creating problems which would grow with time. Staff and non-staff resources would have to be concentrated on the workforce development initiatives in order to move forward rather than regress. As a result, this concentration would not allow ETA sufficient resources for oversight and monitoring and the provision of technical assistance for ongoing programs.

In sum, a reduction of this magnitude would severely hamper ETA's ability to provide quality services to its customers - State and local governments, business and labor; but primarily to the American workers who are seeking assistance to find new and better jobs. It would also further reduce Federal control of existing programs

Pension and Welfare Benefits Administration:

A three percent cut in administrative overhead expenses would exacerbate an already tight portion of the agency's budget. In compliance with the Administration's initiatives to reduce FTE and administrative costs, since FY 1993, PWBA has taken reductions of 5 FTE (or nearly 19 percent) and more than \$300,000 specifically from spending categories within the agency's overhead or program oversight component of the budget and even more from other areas of the agency's budget. A further three percent funding reduction directed at this area of the budget will require, at the very least, another ten percent reduction in FTE from program oversight.

As home base to the Assistant Secretary and two Deputy Assistant Secretaries, and serving as the focal point for policy direction, leadership and management of the pension and employee benefits rights program, the program oversight activity also provides management support in the areas of budget, debt collection, financial and human resources management, labor/employee relations, program-specific training and other administrative activities with absolutely minimal resources. Any further resource cuts can only have deleterious consequences on the agency's ability to continue to provide the essential array of program oversight and support activities.

Pension Benefit Guaranty Corporation:

PBGC's administrative budget for FY 1995 is \$12,030,000. A three percent reduction in PBGC's administrative overhead expenses would mean a reduction of \$361,000. This reduction would have the following impact:

Delay the implementation of new administrative systems, which would impede corporate streamlining efforts.

Increase backlog of responses to inquiries regarding plan coverage, interpretation of PBGC rules, and other aspects of PBGC operations.

Employment and Standards Administration:

A three percent cut in administrative overhead expenses in the Employment Standards Administration would have the following impact:

- Forego hiring the one FTE in Program Direction and Support (PDS) that was related to the enforcement initiative. The loss of this FTE would restrict the development and implementation of modern technology and computer-based investigation resources requested as part of the enforcement initiative.

Forego the \$25,000 for PDS that was part of the agency training initiative. This money was to be used to fund training for financial staff on the Department's new accounting system, for the preparation and presentation of financial statements,

and to keep financial staff abreast of current Chief Financial Officers Act policy issues, accounting trends, and related financial matters.

In order to accommodate the remainder of the reduction, a nine day furlough or a reduction of four FTE would be necessary for PDS with the following consequences:

Diminished financial management.

Agency training would be hampered. This is especially critical given the number of new investigators, compliance officers, and claims examiners (for the expanded Periodic Role Management Project) that will need training in FY 1995.

Occupational Safety and Health Administration:

A three percent reduction in administrative and overhead expenses would cause:

Elimination of program studies to evaluate agency activity.

Delays in response time for financial processing.

Mine Safety and Health Administration:

A 3 percent cut from the Program Administration budget activity represents \$264,000. Since over 90 percent of the expenses in this activity relate to salary costs or fixed expenses, such as space rent, a reduction of 5 FTE would be required. This would impact MSHA's enforcement staff through diminished administrative support for the procurement of necessary supplies, equipment, motor vehicles and office space and for the payment of travel vouchers. Delays could be expected in filling vacant positions and responding to public and Congressional inquiries. The Agency could also be subject to interest penalties for late payments to vendors.

Bureau of Labor Statistics:

A three percent across-the-board reduction in administrative overhead expenses would cause increased hardship within BLS. The 1994 Budget availability for BLS has already been impacted by absorbing the pay raise effective in January, and a rescission of over \$1 million. Although BLS would continue to look towards non-compensation areas to find potential savings, as we get further into the fiscal year, the reality is that the availability of funds in non-compensation object classes dwindles. Depending on the timing of the decision to take a reduction of this size, the only object classes that could produce the savings necessary may be personnel compensation and benefits. If this is the case, BLS could potentially be required to furlough its staff for one day.

Departmental Management:

In the "Program Direction and Support" activity, a reduction of \$755,000 would severely impair implementation of the Department's enforcement initiative, resulting in both the cancellation of customer surveys aimed at determining how the Department can communicate with its customers more efficiently on an on-going basis and precluding establishment of uniform protocols and standards for regulatory information necessary to disseminating this information both to the public and within the Department. It would also eliminate the request for an additional 10 FTE for the Office of the Secretary to support all DOL priorities and programs. The Department's has assumed an expanded role in implementing the Administration's programs directed to the American worker and workplace. Denial of this increase will seriously affect the Secretary's ability to provide the overall coordination and management necessary to achieve the Administration's goals in this vital area.

Office of the Inspector General:

A three percent cut would require a reduction of two FTE in the Program Direction (PD) activity. This activity provides overall management and direction; policy development, planning and review; legal counsel; legislative and regulatory assessment; and resources management including personnel, procurement, financial, information, and administrative/management support functions. PD would curtail some of its activities in the above areas, hampering services to components both in and outside the OIG.

The impact on computer and communications operations and administration is of particular concern. Maintenance, software support and upgrades and licensing agreements would be canceled. This would lead to a reduction in the number of computers available to do audit and investigative work in the OIG-- curtailing the ability to audit entities with computer-based data, capture audit data and present audit results as well as support for OIG management information and administrative applications. The network that connects 35 OIG locations through electronic mail would be vulnerable. Finally, services, such as graphics support would be eliminated and slower response to users requiring routine computer assistance would occur.

Reduction in Discretionary Budget Authority

Question. What would be the impact, agency-by-agency, of a three percent across-the-board cut in total discretionary budget authority?

Answer: Over the past few years, the Department has been required to absorb the costs of several pay increases and other across-the-board cuts to meet overall budget constraints. For example, the DOL appropriation acts for FY 1992 and 1993 included general provisions for across-the-board cuts to meet spending caps. DOL is absorbing over \$25 million in locality pay costs in FY 1994 as well as a rescission of \$4.0 million. In addition, DOL's FTE levels were reduced by 181 in FY 1993, 271 in FY 1994 and 273 in FY 1995 to comply with the President's goal to reduce Federal employment, and the budget was reduced by a total of \$21.4 million in FY 1993-1994 for administrative cost reductions required by executive order. Further administrative cuts are already identified in FY 1996 through FY 1998.

The Department has reached a point where significant savings can no longer be achieved in support and non-personnel cost areas. It will be exceedingly difficult, if not impossible, to absorb further reductions, no matter how small, without having a direct adverse impact on the American worker. This includes providing training and job opportunities for the unemployed, providing timely benefits for the unemployed, incapacitated Federal employees and coal miners and certain pensioners, ensuring a safe and healthy workplace, protecting the legal rights of vulnerable workers, protecting pensions and providing essential statistical information for national policy and decision-making.

In view of this, the Department has serious concerns about using additional across-the-board reductions to accommodate spending caps. Instead, if reductions are necessary, we would prefer to target them to specific areas. We would be available and willing to work with the Subcommittee to identify those programs.

A three percent across-the-board cut in discretionary budget authority would have the following impact:

Employment and Training Administration (ETA):

A three percent reduction to Employment and Training Administration discretionary accounts would result in a reduction of \$300

million. An across-the-board reduction would have the following impact on programs and activities.

Program Administration Appropriation

A 3 percent reduction to ETA's Program Administration appropriation is approximately \$4,300,000. This reduction would lower the number of FTE in ETA by approximately 56, to a level of 1,591 FTE. The current FY 1994 ETA ceiling is 1,669 and the 1995 request is 1,647.

This reduction would have a major adverse impact, coming on top of a 22 FTE reduction and a 3 percent administrative cost reduction already built into the budget. This reduction would include 14 FTE that ETA was planning to use to assume its leadership role in implementing the President's workforce development strategy including the Re-employment Act, School-to-Work, and a major Job Corps expansion.

The reduction from the FY 1995 plan would result in delays in reviews, inspections, grant approvals and create backlogs in areas such as alien certification. The reduction would also severely restrict staff training, creating problems which would grow with time. Staff and non-staff resources would have to be concentrated on the workforce development initiatives in order to move forward rather than regress. As a result, this concentration would not allow ETA sufficient resources for oversight and monitoring and the provision of technical assistance for ongoing programs.

In sum, a reduction of this magnitude would severely hamper ETA's ability to provide quality services to its customers - State and local governments, business and labor; but primarily to the American workers who are seeking assistance to find new and better jobs. It would also further reduce Federal control of existing programs

TRAINING AND EMPLOYMENT SERVICES APPROPRIATION

JTPA PROGRAMS FOR THE DISADVANTAGED:

The reduction would result in approximately 48,300 fewer participants being enrolled in the Adult and Youth Training programs, the Summer Youth employment program, and in the Native Americans and Migrants programs.

JOB CORPS

The reduction equates to \$34.7 million and the entire reduction would be applied to the construction budget to complete the 8 centers previously authorized in 1993 and 1994. Funding to complete these 8 centers would be deferred to FY 1996. First year funding for the 6 new centers planned in 1995 would not be reduced, however, funding for existing Job Corps centers would not be reduced.

DISLOCATED WORKERS

The reduction would equate to about \$44 million to the new comprehensive program to assist dislocated workers. Approximately 22,000 fewer workers could be assisted.

SCHOOL TO WORK OPPORTUNITIES

A 3 percent reduction equates to \$4.5 million which would result in reductions to grants for implementing the School-to-Work system.

OLDER AMERICANS

The reduction would result in 2,700 fewer participants obtaining employment in the Community Service for Older Americans program. This reduction would come on top of a 4 percent reduction already built into the 1995 request which reduced the number of participants by 3,300.

UNEMPLOYMENT INSURANCE PROGRAM

A reduction of \$53 million (3% of the FY 1995 request) to the Unemployment Insurance program would force States to reduce staff, resulting in delays in benefit payments, reduced tax enforcement and a deterioration of quality controls which will cost both the States and the Federal government funds. Although the benefit payments are mandatory, as required by law, inadequate numbers of State staff would be available to deliver the benefits. This, in combination with a reduction to the Employment Service program, could well force States to close local offices.

EMPLOYMENT SERVICE

A 3 percent reduction equates to \$27.5 million for employment service programs, \$25.4 of which would be from State grants for public employment systems. This reduction would reduce the number of job placements, and jobs available, through the employment service. This reduction also, in combination with an unemployment insurance service reduction, would likely force States to reduce staff and close local offices.

ONE-STOP CAREER CENTERS

A 3 percent reduction equates to \$7.5 million which would impose reductions in grants to States for implementing the new one-stop career centers.

Office of the American Workplace (OAW):

In the Office of the American Workplace, a three percent reduction in total discretionary budget authority would result in a cut of \$1,026,000. This cut would eliminate proposed funding for workplace programs research, pilots and demonstrations that would fund initiatives to encourage workplace transformation in a variety of industries. This reduction would eliminate existing initiatives to develop practical data and information critical to the business, labor and policy-making community related to innovative workplace practices. Specifically, OAW would not be able to pursue the following activities --

Research the correlation between high performance workplace practices and corporate financial results, and enhance the use of measures to evaluate high performance work practices by investors, managers, directors and unions to foster the diffusion of these practices throughout the economy and educate the investment community to the long-term business needs;

Create and support community-based outreach networks of service providers to disseminate resource materials and provide assistance to labor unions, managers and labor management committees, and other institutions on new workplace approaches and new work systems to leverage their resources to diffuse high performance workplace practices and enhance the competitiveness of small and medium-sized businesses at the local level; and

Identify and diffuse best practice workplace practices and engage in a comprehensive diffusion strategy designed to convince decision makers of the need for change and provide them with practical, experiential information to enhance their ability to create and sustain workplace change.

Pension and Welfare Benefits Administration (PWBA):

Over the years, the Pension and Welfare Benefits Administration has witnessed phenomenal growth in the value of plan assets, a proliferation in pension and welfare arrangements as well as in the types of investment vehicles. Agency responsibilities include regulation and enforcement of approximately 730,000 private sector pension plans and 4.5 million private sector welfare benefit plans covering an estimated 200 million participants and controlling about \$2.3 trillion in assets.

A reduction of three percent in PWBA's discretionary budget authority would seriously impair the agency's ability to carry out an effective regulatory and enforcement program.

In essence, a three percent funding reduction would effectively translate into a reduction of approximately 39 FTE (or six percent below the FY 1995 request level). Nearly 88 percent of PWBA's FTE comprise the agency's regulatory and enforcement efforts. Consequently, reductions of the magnitude proposed would have serious adverse impact on the agency's ability to carry out its ERISA enforcement and regulatory program.

Maintaining an adequate level of resources is critical if PWBA is to remain an effective deterrent to pension and health plan fraud and abuse. If the public is to continue to support a private system, then we must demonstrate that we can ensure its integrity. The proposed cuts would produce a significantly weakened enforcement presence and the logical conclusion is the likelihood of a significant number of health care fraud and abusive practices.

A reduction of this magnitude would diminish the agency's capacity for carrying out its regulatory and enforcement efforts and this reduced capability would threaten the security of millions of workers and retirees, substantially increase the PBGC's exposure to potential liability, and the disconcerting prospect of inherent loss of public confidence in private pension and health systems.

Pension Benefit Guaranty Corporation (PBGC):

PBGC's total discretionary budget for FY 1995 is \$12,030,000. A three percent reduction would mean a reduction of \$361,000. This reduction would have would have the following impact:

Delay the implementation of new administrative systems, which would impede corporate streamlining efforts.

Increase backlog of responses to inquiries regarding plan coverage, interpretation of PBGC rules, and other aspects of PBGC operations.

Employment Standards Administration (ESA):

A three percent cut in discretionary budget authority in the Employment Standards Administration would have the following impact:

Forego most of the \$1 million requested for the training initiative. Given the limited amount in the base for training, this reduction will complicate successful implementation of and support for the enforcement initiative and reinvention activities.

Forego hiring all of the additional 40 FTE requested as part of the enforcement initiative.

The amounts requested for enforcement travel and enforcement ADP would be reduced by approximately one-half. Thus, not only would ESA's enforcement programs forego the opportunity to strengthen their presence in the workplace through additional enforcement staff, but they would also be denied the full funding necessary to get current employees to the workplaces to conduct investigations and ESA would be unable to equip investigators with modern technology and computer-based investigation support. When combined with the decision to forego hiring the 40 enforcement FTE requested, the result would be reduced enforcement related outputs of, in most cases, two to three percent.

Forego hiring 27 of the requested 105 FTE for the expansion of the Periodic Role Management project at a loss in future

savings in workers' compensation benefit costs of approximately \$21 million through FY 1999.

Occupational Safety and Health Administration (OSHA):

A three percent reduction in overall discretionary budget authority would cause:

A reduction of 4,100 safety and health inspections in workplaces employing over 500,000 workers.

OSHA's ability to conduct targeted inspections would be reduced and the agency would be unable to fully monitor existing Corporate Settlement agreements.

A proportionate reduction of over \$2.0 million for State operational grants.

A reduction of 750 consultation visits to small, high hazard employers who employ approximately 30,000 workers. Over 6,000 workplace hazards would remain undetected.

Safety and health training for 1,200 private sector personnel would be eliminated, as well as 2 training and education grants to private, non-profit organizations.

100 planned Voluntary Protection Program (VPP) participants employing approximately 72,000 workers would be eliminated.

Mine Safety and Health Administration (MSHA):

Over the years, across-the-board cuts, pay absorptions and other reductions have required MSHA to make substantial cuts in non-personnel related expenses. The Agency has reached the point where no further significant savings can be achieved in these areas without serious impact on the ability of our inspectors to perform their duties.

A three percent cut in discretionary budget authority represents \$6,096,000 and would, therefore, require a decrease of 108 FTE. This cannot be effected by attrition alone. In addition to a hiring freeze, up to 6 furlough days could be required, although MSHA would make every effort to avoid furloughs through cuts in other areas.

In the Coal and Metal/Nonmetal Enforcement programs, inspections would be cut by 3,000 which could impact the completion of annual inspections mandated in the Mine Act--four at underground mines and two at surface operations. In addition, special inspections to examine critical hazards associated with gassy mines, roof control, mine ventilation, and electrical problems would be cut by five percent. This includes special programs that target for attention dangerous conditions with the potential for causing major accidents from explosions and roof falls. Experience shows that compliance with safety and health standards at mines drops sharply when inspector presence is reduced. This results in increased accidents, injuries and deaths of miners as well as the slow erosion of their health.

Delays could be expected in the assessment and collection of civil penalties, undermining the effectiveness of MSHA's enforcement efforts. Timeliness of MSHA's penalty process has been an important tool to encourage compliance with safety and health standards, and that is MSHA's goal--to achieve compliance so that accidents, injuries and deaths are prevented.

Reduced educational and technical services would adversely affect the support provided to MSHA's Enforcement programs designed to solve compliance problems and to carry out special programs to

reduce accidents and injuries. If miners are not knowledgeable about the dangers they face and if the mines do not possess the technical expertise necessary to correct problems, the risk rises dramatically for accidents, injuries, and deaths. This is especially evident in the case of small coal mines. It is also true for those nonmetal surface operations that are exempt from the training requirements of the Mine Act.

Bureau of Labor Statistics (BLS):

A three percent cut for all funds requested in 1995 would have a devastating impact. Major program cuts would be required and several furlough days would almost certainly need to be implemented. Among the possible program impacts are:

Employment and Unemployment Measures -- The Nation's basic unemployment measure comes from the Current Population Survey (CPS), which collects data monthly from a sample of 60,000 households. The budget cuts needed to achieve a reduction of this size would significantly reduce the sample size of the CPS. This could eliminate the estimates of unemployment for the largest States and the metropolitan areas of New York and Los Angeles that come from the CPS, and would undermine the reliability and accuracy of the unemployment estimates for the Nation. It also would seriously erode the quality of the model-based estimates of unemployment provided by the Local Area Unemployment Statistics (LAUS) program for the remaining States and all local areas.

In addition, since so many Federal and State programs distribute funding to States and local areas based on their individual unemployment levels, inaccurate measures would cause misallocation of billions of dollars.

Labor Market Information -- The State Employment Security Administrations collect a wide variety of labor market information in cooperation with the Bureau of Labor Statistics (BLS). A three percent budget reduction could dramatically reduce the funds BLS provides the States for this effort, and the States would either have to fund these programs themselves or lay-off the workers in each State that conduct them.

In addition, the data from this network that would be damaged include the Current Employment Statistics (CES) and the ES-202 programs. The payroll statistics, including monthly employment levels, from the CES are among the earliest economic indicators available each month and are used to gauge the health of the U.S. economy in terms of job creation, and average earnings, and average work week. Unreliable employment estimates from the CES could cause confusion in financial markets and throughout the economy. Data the States provide from their Unemployment Insurance files in the ES-202 program form the universe of firms from which most BLS survey samples are drawn. Cuts of this magnitude in Labor Market Information funding, therefore, reduce the accuracy of economic measures from BLS labor force, price, and wage programs.

Consumer Price Index (CPI) -- The budget cuts needed to achieve a three percent reduction would cut the sample size and number of price quotations collected for the CPI, and therefore reduce the reliability of this principal source of information concerning inflation in the U.S.

Departmental Management (DM):

Within the Departmental Management Salaries and Expenses (DM S&E) appropriation, a three percent across-the-board cut in discretionary budget authority would result in a reduction of \$5,886,000 - \$5,170,000 in Federal funds, \$706,000 in Black Lung Disability

Trust Funds, and \$10,000 in Unemployment Trust Funds. A three percent across-the-board cut in administrative overhead expenses would involve the "Program Direction and Support" activity and result in a reduction of \$755,000.

In the "Program Direction and Support" activity, a reduction would severely impair implementation of the Department's enforcement initiative, both resulting in the cancellation of customer surveys aimed at determining how the Department can communicate with its customers more efficiently on an on-going basis and precluding establishment of uniform protocols and standards for regulatory information necessary to disseminating this information both to the public and within the Department. In addition, the 10 FTE requested for the Office of the Secretary would be eliminated. The Secretary's major goals are to provide first, new and better jobs to the American worker and to reinvent the Department. Loss of these FTE will seriously hamper the ability to provide the overall coordination and oversight needed to assure success of the Administration's investment program in employment and training as well as internal reinvention activities that cross traditional DOL agency lines.

In the "Legal Services" activity, a reduction would result in the inability of the Office of the Solicitor to provide adequate support to the Department's enforcement initiative. Litigation backlogs will develop in the Office of Federal Contract Compliance Program, Employee Retirement Income Security Act and Wage-Hour enforcement programs. Implementation of productivity improvements involving ADP enhancements will be deferred, precluding DOL attorneys from sharing pleadings and briefs electronically. Work on new regulatory projects involving health care reform will be deferred. In the Black Lung area, this reduction would result in approximately 140 Black Lung cases being concluded in FY 1995.

In the Bureau of International Affairs, a reduction of would result in the failure to be able to fully implement the provisions of the North American Free Trade Agreement.

In the Office of the Assistant Secretary for Administration and Management, which includes the Civil Rights activity, the combined reduction would result in increased and more lengthy disruptions to the Department's Local Area Networks (LANs). In the "civil rights" area, a 10 percent reduction would be seen in enforcement activities related to compliance reviews.

In the Adjudication activity, support for OSHA reform-related activities involving the Office of Administrative Law Judges would be eliminated, and backlogs would develop in this area. In the Black Lung area, 10 additional positions would be eliminated at the Benefits Review Board, resulting in 125 fewer Black Lung dispositions and backlogs returning in other Black Lung-related case processing areas.

A reduction in the President's Committee on Employment of People with Disabilities would reduce funding for the Job Accommodation Network (JAN) resulting in the reduced ability of the Committee to market JAN services and in a reduced number of people with disabilities being supported in their efforts to find meaningful employment in today's society.

In the Women's Bureau funding requested for the support of the Family and Medical Leave Act (FMLA) Commission on Leave would be eliminated. A reduction in the Office of the Chief Financial Officer, would cut in half planned enhancements in managerial accountability in financial management processes.

Finally, a reduction in the enforcement automation fund would slightly reduce implementation of the Department's enforcement initiative, because all of these funds will be heavily competed for

by the DOL enforcement agencies in an effort to upgrade their ADP capabilities and enhance the productivity of front-line workers.

Office of the Inspector General (OIG):

A three percent reduction in overall discretionary budget authority would have the following impact:

A three percent cut would equate to a 6.5 FTE reduction in Office of Audit (OA). This would decrease the number of audits to evaluate management control systems which would improve systems to prevent fraud, waste and abuse in departmental programs.

OA's audit contract funds would be reduced. This would adversely affect employees in small and/or minority owned and operated CPA firms. Federal employees would be shifted into Chief Financial Officer Act work on financial statements and reviewing agency performance measures, detracting from other audit work.

Travel funds would be cut back, delaying the completion of scheduled nationwide audits of the Job Corps and Dislocated Workers programs at a time when they will greatly expanded. Timely information on effectiveness is critical to sound decision-making. Also, delays would have a domino effect, causing postponements and possible cancellation of other planned audits.

A three percent cut would equate to a three FTE reduction in the Office of Investigations (OI). At this staffing level of 96 FTE, OI would be unable to react to problems that are labor-intensive and still provide general investigative support to the Department. For example, OI will no longer be able to sustain its successful investigations of organized groups that have defrauded the Unemployment Insurance Program of millions of dollars.

OI now covers the entire nation with 76 field agents who have a presence in 18 locations. Agents must travel to perform their responsibilities. Reductions in staff and travel funds will make it nearly impossible to maintain minimally adequate coverage.

A three percent cut in the Office of Labor Racketeering (OLR) would equate to a 3.5 FTE reduction. In the last three fiscal years, OLR has lost a total of 13 FTE. This cut would reduce OLR's FTE level to 111, a decrease of 13 percent from its previous level of 128 FTE. This will limit OLR investigations. In the longer term, continued staff reductions will require withdrawal from some geographic areas and the closing of offices. Travel, training, and investigative expense payments to informants and undercover operations would be reduced. This will diminish ability to conduct criminal investigations. Some investigative activity would be impossible. Service to our primary customers, federal prosecutors, would be reduced to investigations involving limited travel or expenses. Particularly affected would be investigations of employee benefit plans, including Multiple employer Welfare Arrangements (MEWAs) and bogus unions because of the travel involved. This will open the door to fraudulent operators who have in the past left thousands of victims with millions of dollars in unpaid claims.

Assistant Secretary for Veterans' Employment and Training (ASVETS):

A three percent reduction in discretionary budget authority in the Office of the Assistant Secretary for Veterans' Employment and Training, would result funding for 51 fewer State positions in the Disabled Veterans' Outreach Program (DVOP), resulting in services being provided to approximately 29,000 fewer veterans. A total of 44 fewer State positions would be funded in the Local Veterans Employment Representative (LVER) program, resulting in services being provided to approximately 25,000 fewer veterans. Of the total reduction of \$5,708,000 made in this program, \$645,000 would be cut in the Transition Assistance Program (TAP), cutting workshops by approximately 50 percent and reducing the number of separatees served from the planned level of 130,000 to approximately 65,000.

LOCAL CAPACITY TO ABSORB DISLOCATED WORKER AND ONE-STOP INCREASES

Question. Your increases for dislocated workers and one-stop shopping are fairly sizeable. Does the capacity exist in the State and local communities to expand at this rate?

Answer. We believe that States and localities will be able to use new funding quickly and efficiently.

Past experience has shown that given sufficient planning time, the job training system responds well to implement new policies and meet new service demands. A recent example of this is the Summer Youth Employment Program where in 1993 States and localities absorbed a substantial increase in resources and implemented a change in program design, introducing a new educational dimension to summer employment. By all accounts, the system handled the challenge without faltering and achieved positive results.

Under the Re-Employment Act (REA), we have an added advantage. The REA provides considerable discretion to States and localities on exactly how major system changes will be handled and how new resources will be used. Given sufficient lead time for planning, States and localities will be able to use new resources to efficiently and effectively improve customer service. Also, a significant emphasis will be placed on capacity-building, which will allow for the development of the multi-disciplinary staff capabilities needed for support of this and all other workforce initiatives. These resources will be aimed at improving the competencies of Federal, State and local government personnel to design, plan and implement programs while focusing on such valuable skills as assessing clients, brokering/case managing services and coordinating system workforce development activities. This will then result in staff capable of meeting the challenge of effectively serving those most-in-need.

JTPA AND JOBS TRACKING SYSTEM

Question. It is my understanding that an individual can complete training under the Job Training Partnership Act and then turn around and take another training program under the JOBS program -- that there is no tracking -- no way to tell if programs are working -- or if an individual is simply going from one training program to another. Are you taking any steps to initiate a tracking system between job training programs?

Answer. As you are probably aware, participation in JTPA is voluntary while participation in the JOBS program is mandatory for those who meet specified criteria. Thus, it is not unlikely that an individual could participate in a JTPA training program and then at some later time be required to participate in the JOBS program. There are strong linkages and coordination between the JTPA and JOBS in order to reduce duplication and increase program effectiveness. We have recently implemented a reporting system that will track participants in JTPA by social security number. This will vastly increase our knowledge of what services participants are receiving.

UNCOLLECTED DISALLOWED COSTS IN JOB TRAINING GRANTS

Question. The Inspector General's office has reported on a number of training grants where sizable amounts of disallowed costs have gone uncollected for years. Why does it take so long to recoup disallowed costs?

Answer. The appeals process associated with disallowed costs is frequently lengthy and causes the delay in recovering the costs. The appeals process flows from the issuance of the Final Determination. The request for the hearing must be filed by certified mail "return receipt requested" not later than 21 days after receipt of the Final Determination. The hearing process is then in the hands of the Administrative Law Judge (ALJ) and usually takes approximately two years (and sometimes longer) to complete. A contractor or grantee may then appeal the ALJ's ruling to the Secretary of Labor. Under JTPA, the Secretary is required to respond within 180 days. After the Secretary issues a decision, which constitutes final agency action, the contractor/grantee may appeal the case through the court system to the U.S. Supreme Court. Also, after the Secretary's decision is rendered, the Employment and Training Administration (ETA) places the case in debt collection. Three progressively stronger demand letters are sent approximately 30 days apart. Thirty days after the third demand letter, a notice is sent to the contractor/grantee that the case is being referred to the Department of Justice for collection through litigation, termination or compromise. Once the case is referred to the Department of Justice, the time frames are no longer under the control of ETA and the Department of Labor. Once the Department of Justice assumes control of the case, litigation and due process can take a number of years to complete.

ETA has responded to the Inspector General with complete, detailed information on all cases in question.

IMPOSITION OF PENALTY AND INTEREST ON QUESTIONED COSTS

Question. Would you agree with the Inspector General's recommendation to impose interest and penalty costs from the time the costs are first questioned, to act as an incentive for grantees to speed up resolution of questioned costs?

Answer. No. Interest and penalty costs should be imposed from the time the Final Determination is issued because it is a statutory and regulatory requirement that the agency has 180 days to issue a Final Determination. Until the Final Determination is issued, there is no debt established on which to impose interest and penalty charges.

MINERS' HEALTH

Question. Mr. McAteer, you mentioned in your prepared statement that efforts to detect, punish, and deter dust level violations will become an increasing priority at the Mine Safety and Health Administration. You also indicated a conference will be held to focus on miner's health issues. What is the current status of these activities, and what are your specific plans for promulgation of new regulations.

Answer. Exposure to respirable coal dust destroys miners' health and should be a thing of the past. Following disclosure in 1991 of widespread tampering with respirable dust samples taken by mine operators, MSHA issued over 4,700 citations and \$7.0 million in civil penalties for dust sample tampering. Criminal prosecutions were initiated, and to date MSHA has obtained 137 pleas and convictions for dust-related fraud. While the incidence of falsified dust samples has dramatically dropped, MSHA continues to uncover fraudulent dust sampling activities.

MSHA conducted a comprehensive review of the dust program and is now implementing changes to improve and strengthen it. In addition to examining all operator samples, MSHA's dust sampling and monitoring inspection procedures have been revised. The Agency is also in the process of revising the dust regulations to enhance the integrity of the operator's sampling program, provide for monitoring of dust exposures under more representative operating conditions, improve the quality and effectiveness of dust control plans, and strengthen the dust sampling certification process.

Technological improvements will also help deter dust level violations. More tamper-resistant cassettes, which recently became commercially available, now account for over 85 percent of those used in the operators' sampling program. A new sampling pump with the capability to indicate if it was shut off during sampling is undergoing field testing. MSHA is also involved with the Bureau of Mines in their efforts to develop a continuous dust monitor and a monitoring system for dust control measures.

Dust is only one of the health hazards faced by miners. A miner should be able to enter the mines as a young man or woman and work until retirement age and not be required to sacrifice his or her health as a part of the job. Accordingly, MSHA intends to focus on the long neglected area of miners' health this summer at a conference of Agency health professionals. The goal of the conference is to identify and prioritize health hazards and to develop program improvements that increase the inspector's ability to recognize, evaluate, and provide solutions to health hazards.

Following are the specific health regulations MSHA plans to work on during FY 1995.

Respirable Dust

MSHA plans to develop a proposed rule updating and improving the coal mine respirable dust standards. This rule is one of the Agency's top regulatory priorities. The proposed rule will incorporate recommendations of an inter-agency task group for improving the accuracy and effectiveness of the coal dust program.

Air Quality

This final rule would include a comprehensive update of most of MSHA's harmful contaminant standards, with the exception of respirable coal mine dust which is addressed in a separate rulemaking. The rule would address methods of monitoring and controlling exposures and incorporate updated permissible exposure limits and standards for use of respiratory protective equipment.

The final rule also would update asbestos standards; establish precautions for handling restricted-use chemicals; provide for miner observation of monitoring; provide for notification to workers of overexposures; allow miner access to exposure monitoring records; and address the use of medical surveillance and transfer for miners required to use respirators and for miners using certain carcinogens.

In February 1994, MSHA published a portion of the air quality rulemaking as a final rule to address immediate health concerns related to abrasive blasting and drill dust control. Whenever miners conduct abrasive blasting or drilling, they are exposed to serious health hazards that require implementation of specific dust controls before engaging in this activity. The final rule retains existing requirements for rock drilling operations at metal and nonmetal mines and underground coal mines and establishes new requirements for rock drilling operations at surface coal mines and surface work areas of underground coal mines.

Noise

Hearing impairment may be a serious occupational hazard in the mining industry. Many miners are consistently exposed to noise levels that are near maximum levels currently permitted by MSHA. MSHA is developing a proposed rule to address this potentially serious problem.

Diesel Equipment

During the past decade, diesel-powered equipment has been introduced into underground coal mines in increasing numbers. MSHA does not have regulations that specifically address the health hazards associated with the particulate in the exhaust emitted by diesel-powered equipment. MSHA is in the early stages of examining the appropriateness of developing a permissible exposure limit to control miners' exposure to diesel particulate. In January 1992, MSHA issued an advance notice of proposed rulemaking in which the Agency requested public comments on a series of issues relating to health effects, methods of monitoring exposure, duration and frequency of exposure, and technological and economic feasibility. MSHA is continuing to review available data and studies on the use of diesel equipment and the particulate emissions from diesel equipment to develop a proposed rule.

Bloodborne Pathogens

MSHA has identified mine rescue, emergency medical treatment, and first aid as activities in mining which pose a high risk of exposure to bloodborne infectious diseases. Because most mines are distant from professional health care providers, miners often must provide more extensive emergency care than general industry employees. MSHA will be evaluating personal protection, training, vaccination, disposal, and other controls necessary to protect persons engaged in these high risk activities in mining. MSHA will consider OSHA standards and CDC guidelines in developing a proposed rule.

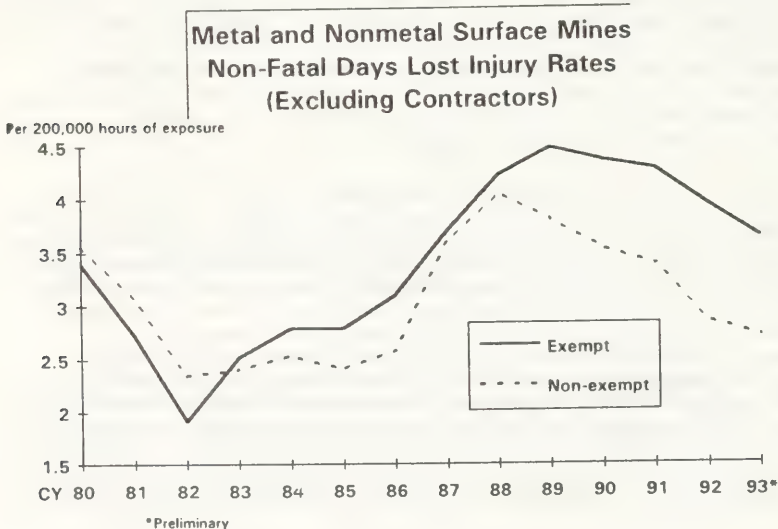
TRAINING RIDER

Question. Your budget again requests the removal of the bill language prohibiting your agency from enforcing the training provisions and regulations at certain nonmetal mines. Please describe how removal of the rider will assist in your overall objective of improving miners safety and health.

Answer. Our records show generally that both fatalities and lost-time injuries at mines exempted from training requirements by the training rider have been significantly higher than those at operations where MSHA is not prohibited from enforcing miner training requirements. In fact, non-fatal injury rates at exempt operations are also higher than comparable rates at surface coal mines.

Prorated according to hours of worker exposure, operations covered by the rider have suffered about 150 more fatalities and over 6,000 more lost-time injuries since 1980, when Congress first attached the appropriation rider, than surface operations not covered by the rider. We do not suggest that all of the additional fatalities and injuries would have been prevented if the enforcement restriction had not been placed on MSHA. However, keeping in mind the universally recognized importance of training in improving safety in the workplace, it is reasonable to believe that some of the fatalities and injuries at sand, gravel, surface stone, surface clay, colloidal phosphate, surface limestone, and shell dredging operations could have been avoided if MSHA had not been prohibited from enforcing its training requirements at those operations.

Following is a graph comparing the non-fatal days lost (NFDL) accident rates of exempt and non-exempt operations. Because of the difference in man hours of worker exposure between the two categories, it is appropriate to compare rates rather than actual numbers.



Question. What is your response to those in the sand gravel industry who indicate the training requirements are excessive and too great a burden on small businesses?

Answer. The minimum training requirements mandated in the Mine Act are reasonable given the serious consequences of unsafe acts which may occur due to a lack of hazard awareness or a lack of knowledge concerning the health and safety aspects of one's job. The hazards found at small mines are just as serious as those found at other mines and the consequences are just as severe.

The Mine Act requires underground miners to receive no less than 40 hours and surface miners no less than 24 hours of training before starting to work at a mine. Both surface and underground miners are required to receive no less than eight hours of refresher training each year. Also, miners are required to receive safety related task training when a miner is assigned to a new job.

The legislative history of the Mine Act indicates that Congress recognized mines vary greatly not only in size but also in mining methods and production processes. As a result, the Mine Act establishes minimum training requirements, but places the responsibility for developing training plans with the individual mine operators. Under this scheme, each operator develops and submits to MSHA for approval a plan which takes into account the specific hazards to which his or her workers are exposed. Thus a small mine operator's plan would and should differ significantly from a training plan developed by an operator of a large mine.

The majority of metal and nonmetal mines can be considered "small businesses". In recognition of the concerns expressed by members of the now "exempt" operations regarding the impact of 24 hours of pre-employment training on small, intermittent businesses, MSHA regulations allow an operator to provide up to 16 hours of the 24 hours of training for new miners within a 60 day period after the assignment of work duties. In addition, while the regulations do require that the training be provided by a certified person, MSHA recognizes that many miners and foremen possess the requisite knowledge to conduct the training. Third, MSHA's regulations stipulate that the statutorily required 8 hours of annual refresher training may be given in 30 minute segments. In essence, the Agency promulgated regulations taking into consideration the impact on small mine operator and developed regulations which it believes can be used to develop an effective and site specific training program.

Many small surface mine operators, both coal and metal and nonmetal, are able to comply with the training requirements. In our view, the removal of the restrictive language would not only have safety and health benefits, but would also provide a more "level playing field" for all small mine operators.

FAMILY AND MEDICAL LEAVE ACT

Question. Your budget justification indicates you expect 700 compliance actions under the Family and Medical Leave Act in each of fiscal years 1994 and 1995.

How does this compare to the expected level of complaints received and resolved, as well as complaints in inventory?

Answer. Our objective in administering the Family and Medical Leave Act (FMLA) is to resolve 90 percent of all complaints within 30 days of receipt. As a result, we do not expect to maintain any inventory of FMLA complaints. Our budget workload tables assume that we will receive 700 complaints in fiscal years 1994 and 1995 and we will resolve all received. Through the end of February 1994, for the seven months that FMLA has been in effect, we have received 442 FMLA complaints, 391 in the five months of FY 1994. Our experience so far is that the complaints received may be moderately higher than expected.

Question. How many compliance actions have been resolved to date, and how would you classify these cases?

Answer. From August 5, 1993, when the Act became effective through the end of February 1994, Wage and Hour resolved 440 formal complaints filed by employees. These complaints involved allegations that employers: refused to grant FMLA leave; refused to restore an employee to his/her previous position or an equivalent position; refused to restore the employee to equivalent pay/benefits; or, refused to maintain the employee's health coverage while the employee was on FMLA leave.

BILL LANGUAGE TO ACCESS FEES

Question. You are requesting bill language authorizing the Secretary of Labor to establish and collect fees to defray the cost of certain Employment Standards Administration activities.

How much do you expect to collect and spend in fiscal 1995, and for which specific activities?

Answer. We estimate that Wage and Hour would collect \$1.6 million in user fees for a full fiscal year. The funds collected will be deposited in the miscellaneous receipts account of the Treasury and will not be used to defray the costs of ESA activities, but rather to offset the monies appropriated to perform these services. Depending on the timing of enactment and steps needed to implement the user fees, the amount collected could be considerably less in the first year (FY 1995).

It is proposed that user fees be authorized to be charged to cover the costs of Wage and Hour providing those services which are necessitated by requirement of law and, generally, without which the user would not be allowed to conduct certain employment practices. Services subject to a user fee include the processing of applications for registration under sections 102 and 103 of Migrant and Seasonal Agricultural Workers Protection Act; applications for homeworker certificates issued under section 11 and special minimum wage certificates issued under section 14 of the Fair Labor Standards Act.

SAVINGS FROM PERIODIC ROLL MANAGEMENT PROJECT

Question. Your written testimony indicates that the current pilot project to return injured Federal employees to work, called

the Periodic Roll Management Project, produces benefit cost savings about 14 times greater than the original administrative cost.

How solid are these savings in workers' compensation benefits?

Answer. Because early actual results of the four-office project greatly exceeded our original estimates, we revised our savings projections upward. Our current projections and actual project savings have been tracking very closely. Estimates for expansion of the project to the remaining eight FECA offices are also based upon the actual results of the current project.

Question. Why shouldn't these savings be credited to the Appropriations Committee, as an incentive to expanded activities in this area?

Answer. The savings are being credited to agencies in the form of reduced chargeback bills, which result in lower appropriations in the year repayment is due. However, there is a lag time between the time the PRM Project generates reduced outlays from the Special Benefits Fund for workers' compensation expenses and the time the savings are realized by Federal agencies.

Although the actual savings in workers' compensation costs from the PRM Project are calculated on a Fiscal Year basis, Federal agencies are billed for their workers' compensation costs on a Chargeback Year basis which begins on July 1 and ends on the following June 30. The U. S. Postal Service, which accounts for about 26% of all workers' compensation benefit costs, reimburses the Special Benefits Fund the same Fiscal Year in which the outlays occur. Other accelerated payment (usually non-appropriated) agencies (accounting for approximately 4% of costs) reimburse the Fund the following fiscal year, while most Federal agencies (accounting for 67% of costs) reimburse the Fund two fiscal years after the benefits are paid. Approximately 3% of compensation costs are not reimbursable but are paid for through the Special Benefits Fund appropriation. Any savings occurring in Chargeback Year 1993, for example, would be reflected in reduced bills to be paid in FY 1995 for most Federal agencies, resulting in a smaller appropriation for these agencies than otherwise would have been without the PRM Project.

As an illustrative example, for the last Chargeback Year, ending June 30, 1993, the savings from the PRM Project were \$14.5 million. That savings amount translated into a \$3.8 million reduction in the bill to the U. S. Postal Service that was reimbursed to the Fund in FY 1993, a \$0.6 million reduction in bills paid in FY 1994, and a \$9.7 million reduction in bills due in FY 1995. The PRM Project will reduce FY 1995 obligations for workers' compensation benefits by an estimated \$41.5 million. Reductions in Chargeback Year reimbursements due to the Fund in FY 1995, the true savings to Federal agencies, are estimated at \$21.1 million.

We are also proposing the collection of assessments and fees through the Office of Workers' Compensation Programs.

Specifically, a portion of the fair share assessments imposed on certain Federal agencies would be expended for upgrading ESA's major ADP system hardware and software. Fees levied against insurance carriers and self-insurers in the Longshore and Harbor Workers' Compensation Program would be used to provide for oversight of the Longshore Special Workers' Compensation Fund.

In FY 1994 we collected \$19.2 million from Federal agencies subject to Federal Employees' Compensation Act fair share assessments and we expect collections on assessments in FY 1995 to be about \$19 million. We propose to spend \$5.299 million in FY 1995 for RFP development and testing to upgrade ESA's major system hardware and software. The balance of the FY 1995 collections will be deposited into the general Treasury account.

In the Longshore and Harbor Workers' Compensation Program, the Special Workers' Compensation Fund serves as a safety net for injured workers when a self-insured employer becomes insolvent. If that employer's self-insurance reserve deposit is insufficient, the Special Fund will assume its benefit obligations under Section 18 of the Longshore Act. If that happens, other Special Fund contributors may experience an increase in their annual assessment.

In FY 1993, Special Fund assessments and expenditures reached \$114 million. In recent years, the Longshore program has seen an increase in the number of insolvencies among self-insurers and insurance carriers. We have requested an additional \$203,000 in FY 1995, to be generated through fees levied against insurance carriers and self-insurers, to conduct a review of existing self-insurance authorization policies and standards, as well as provide the necessary oversight and maintenance for which the Department is responsible. The review is necessary for ensuring that the best available standards are applied when evaluating applications to protect the Fund against the impact of insolvencies. The additional monies requested will be assessed to the users of the service, i.e. the Longshore insurance carriers and self-insurers.

Question. Is this authorized, and, if so, why do we need special bill language?

Answer. Wage and Hour is not legally authorized to collect user fees without the requested appropriations language.

Fair share assessments are required of certain Federal agencies by Section 8147(c) of the Federal Employees' Compensation Act to pay their fair share of the cost to administer FECA claims filed by their employees. Section 8147(c) provides that these amounts are to be paid to the Treasury as miscellaneous receipts. Current appropriation language authorizes the Secretary of Labor to collect the Postal Service's portion of this assessment and deposit those funds directly into the Special Fund account. Section 8147(c) generally prohibits expenditures from the Special Benefits Fund for administrative costs.

We propose a change to current appropriations language to allow the Secretary of Labor to collect the administrative cost assessment from each of the agencies defined in Section 8147(c)

with the authority to deposit into the Special Fund amounts needed to fund a capital improvement project, namely replacement of ESA's aged computer base, expected to cost approximately \$30 million over four years.

The Longshore Special Workers' Compensation Fund is a private sector fund, financed by assessments on self-insured employers and insurance carriers to pay benefits to injured workers in certain specified circumstances. The Treasurer of the United States is the custodian of the Fund, and the monies are held in trust and are not the money or property of the United States. Disbursements are made from the Fund on the order of the Director, Office of Workers' Compensation Programs. Billing the increased administrative costs to the Fund will allocate the cost to the users of the service. This requires no special appropriations bill language.

FY 1995 PROGRAM INCREASES

Question. Why are you requesting an additional 105 temporary positions for expansion of the FECA Periodic Roll Management project?

Answer. ESA is requesting 105 four-year term FTE and \$8,084,000 to expand the Federal Employees' Compensation (FEC) program's Periodic Roll Management (PRM) Project. The current project, located in four district offices and staffed with 48 term FTE, has already resulted in significant savings to the FEC Special Benefits Fund (over \$22 million through FY 1993 with projected savings of over \$179 million through FY 1999). Expansion of the project to the remaining eight FEC offices will result in additional savings of over \$131 million in workers' compensation costs through FY 1999 at an increase in administrative costs of approximately \$29 million, a return of over four dollars for every dollar spent.

Question. Does your request include resources for training employees?

Answer. ESA's FY 1995 request includes an increase of \$1 million for training our employees, especially our front-line employees. Tight fiscal constraints in recent years have severely curtailed our ability to properly train our workforce, adversely affecting our ability to implement new responsibilities and more effective approaches to accomplishing our mission as well as our ability to increase professionalism, consistency, and productivity within in each individual program. The training funds requested will begin to meet front-line staff training needs that have been neglected far too long.

Question. Does your request include a funding increase for enforcement purposes?

Answer. The Department has developed a three-pronged workforce investment strategy of first jobs, new jobs, and better jobs. As one of the components of the strategy for better jobs, the Department has established an enforcement initiative to better address its evolving law enforcement responsibilities.

Enforcement initiatives have been developed that seek to target the worst actors and offenders, protect the most vulnerable populations, deter violations through the use of significant penalties, and get results more swiftly and efficiently.

To support the Department's overall enforcement initiative, ESA's request includes an additional 40 FTE and \$5.8 million. This request will provide increased resources for enforcement travel and ADP for the Wage and Hour Division and the Office of Federal Contract Compliance Programs. The additional FTE and related funding will be used primarily to mount coordinated enforcement efforts targeted at egregious violators of equal employment opportunity and wage and hour standards. The resources will facilitate restructuring initiatives such as the movement of staff resources from supervisory functions to front-line enforcement, decentralizing enforcement activities, empowering front-line enforcement staff, reengineering work processes, and providing front-line enforcement staff with modern technology and computer-based investigation resources.

CURRENT POPULATION SURVEY

Question. Summarize the changes in the Current Population Survey, and explain how it is progressing.

Answer. BLS redesigned the Current Population Survey (CPS) to improve the quality of the data produced by the survey and to keep the survey up-to-date. The CPS has been improved in two principal ways: by conducting a major revamping of the questionnaire (refining and adding questions) for the first time since 1967, and by automating the data collection process. The new questionnaire, put in place for the first time in January 1994 after several years of research and testing, was updated to help BLS keep pace in accurately measuring major shifts in the U.S. labor market, such as the more prominent role of women, the continuing growth in the service sector, and the growth of part-time and temporary employment. Some of the improvements represented the implementation of recommendations of the National Commission on Employment and Unemployment Statistics in 1979. The automation of the data-gathering process has been done to incorporate advances in survey research methods, as well as data collection technology. The introduction of lap-top computers for use in the field by the Census Bureau enumerators represents a key accomplishment in making the survey "state of the art".

There have been no important technical problems associated with the introduction of the new survey instrument, and BLS's extensive public education campaign appears to have been successful in informing users of the survey data of the changes that were made. Work continues on the remaining activities associated with the redesign. This ongoing work includes research on the effects of the new questionnaire and computer-assisted interviewing on important labor force measures and efforts to develop longitudinal uses of CPS data. A new parallel survey using a sample of 13,000 households began in January 1994, using pre-redesign ("old") CPS questions and collection methodology. This survey is expected to extend the comparisons possible between the "old" and the "new" questionnaire and collection methodology. Finally, the sample for the survey is being redesigned, based on information from the 1990 decennial census; the new sample is being introduced over a 16 month period beginning in April 1994.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

NATIONAL MINE HEALTH AND SAFETY ACADEMY

Question. Provide the amount of revenues received by the Academy for the use of its facilities and for classes for FY 1992, FY 1993, FY 1994, and the projected amounts for FY 1995.

Answer. The revenues for the use of Academy facilities (lodging) and classes (tuition) are provided below.

FY 1992	Lodging	\$152,709
	Tuition	<u>28,056</u>
	Total	180,765
FY 1993	Lodging	\$149,087
	Tuition	<u>15,630</u>
	Total	164,717
FY 1994 estimate	Lodging	\$150,000
	Tuition	<u>35,000</u>
	Total	185,000
FY 1995 estimate	Lodging	\$150,000
	Tuition	<u>35,000</u>
	Total	185,000

Question. Provide the staffing levels at the Academy for those same years.

Answer. The Academy's staffing level (actual FTE) was 68 for FY 1992 and 67 for FY 1993. The budgeted FTE is 64 for FY 1994 and FY 1995.

Question. Please advise how many requests have been made for the use of the Academy, how many were granted, and how many were turned down for FY 1992, FY 1993 and the numbers that are available for FY 1994.

Answer. MSHA has accommodated all mission-related requests for the use of the Academy. Occasionally, this requires alternative scheduling. The specific numbers of course requests are not available for years prior to FY 1993. In FY 1993, there were 293 requests for mission-related courses, and 293 were granted. As of March 31, 1994, there were 47 mission-related requests for FY 1994, and all were granted.

APPROVAL AND CERTIFICATION CENTER

Question. Please provide the number of FTE at this facility for FY 1992, FY 1993, FY 1994 and the number of FTE projected for FY 1995.

Answer. The actual FTE for the Approval and Certification Center was 87 in FY 1992 and 85 in FY 1993. The projected FTE for FY 1994 and FY 1995 is 84.

Question. Please provide the operating budget for this facility in FY 1993, FY 1994, and the amount projected for FY 1995.

Answer. The operating budget for the Approval and Certification Center was \$5,135,000 for FY 1993 and is approximately \$5,200,000 for FY 1994 and FY 1995.

REDUCTION OF BLACK LUNG BACKLOGS AT THE BENEFITS REVIEW BOARD

Question. I note that progress is being made in reducing the backlog of black lung claims at the appeals level under the direction of the Acting Chief Judge. When do you anticipate the elimination of these backlogs?

Answer. The Benefits Review Board began Fiscal Year 1994 with 2,829 pending black lung appeals. Through March of this fiscal year the number of pending cases has been reduced, on the average, by 86 appeals each month (an 18% reduction for the first 6 months of FY 1994). It is projected that there will be fewer than 1,600 appeals pending at the Board at the end of this fiscal year. Assuming the current rates of filings and dispositions, by the end of Fiscal Year 1995, the Board should be working on current appeals and have no backlog.

PERMANENT APPOINTMENT OF CHIEF JUDGE

Question. I note that no permanent appointment has been made for the Chief Judge. When do you anticipate such an appointment?

Answer. Efforts are currently under way to appoint a Chairman at the Benefits Review Board on a permanent basis. While I do not know the exact time when an announcement of the nomination will be made, I hope that it will be in the near future. In the interim, as indicated above, the progress being made at the Board under Judge Nancy Dolder's leadership is impressive. Given our current projection of 2,640 Black Lung dispositions on an annual basis, having fewer than 1,600 Black Lung cases pending at the end of FY 1994 reflects the marked improvements in the status of case processing being made at the Benefits Review Board at this time.

PENDING BLACK LUNG CASES AWAITING OALJ HEARING

Question. Although the budget justification projects no backlog of Black Lung claims, I understand that there are Black Lung claims that have not yet been assigned for hearing. Please provide a list of the number of claims pending assignment, by state, as of March 15, 1994. Also provide the age of the case from the date of receipt to assignment. Please provide information on when you expect those cases to be assigned for hearing.

Answer. Out of a base of approximately 3,000 Black Lung cases received on an annual basis, as of March 15, 1994, there were 372 unassigned Black Lung claims at the Office of Administrative Law Judges. The median age of case was 71 days.

Some of these unassigned cases have been previously assigned and continued at the request of the parties. The reasons for the parties' requests include the inability of the claimants to obtain representatives, sickness or severe weather conditions during this past winter, and scheduling conflicts. Additionally, the majority of these cases are located in cities for which there are not enough claims to comprise a hearing itinerary -- a group of 20-25 Black Lung cases in one hearing location ready for assignment.

Black Lung case assignment reviews are made routinely every two weeks. As shown above by the median age of our cases, we routinely assign cases for hearing within four months of receipt. Because of the remote location of some cases, a small number of cases are held in abeyance for a longer period time until we can fill a hearing itinerary with a sufficient number of cases. Because the bulk of cases unassigned for more than 71 days involve cases where continuances have been requested and granted, as of April 11, 1994, there are no hearing itineraries available for assignment. The listing of cases which you requested by state is being provided under separate cover.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

JOB CORPS SITE AWARD CRITERIA

Question. I would be interested to know what criteria you use when awarding Job Corps sites. You just had a competition where 25 site vied for 9 slots. Will you select your six new sites using the same criteria? What was the rank order of the 16 sites not selected?

Answer. The following criteria were used in the Job Corps site selection process:

- Determination of need for urban/rural at-risk youth by analyzing state level youth poverty rates and existing Job Corps center slots and locations.
- Availability of facilities that could be economically utilized, as well as an assessment of need for new construction.
- Proposal to use state/local resources through contributions/linkages that enhance services and/or reduce the Federal cost of operating a center. It is anticipated that the same or similar criteria will be used.

In regard to the question about criteria to be used for selection of the six new sites, we anticipate that the same or a similar process will be utilized for the selection of sites for the six new centers.

In 1994, the 25 final sites were divided into two groups -- military and non-military locations. Of the nine sites selected, five were closed military bases. All of the sites were viable for locating a Job Corps center. Sites not selected in 1994 can reapply in the 1995 selection process. Specific improvements in facilities offered and linkages proposed should enhance the competitiveness of those sites not selected.

DISCRETIONARY PROGRAM BUDGET CUTS

Question. Secretary Reich, we all face the same caps on discretionary spending. You have made some tough choices in the budget you present today, and I would like to hear the reasoning behind some of them. For example, you propose a \$14.4 million, or 3.6 percent, reduction in Community Service Employment for Older Americans. What is the analytical basis for making your cut at 3.6 percent instead of 3.2 percent or 4 percent?

Answer. We believe the requested level, which is at the FY 1993 appropriated level, to be adequate for the program due to the tight budgetary constraints. In addition, the proposed increase in the Title II-A program will allow for additional older workers to receive training and employment services through this JTPA program for adults, in an effort to place older workers in long-term, unsubsidized employment. No participants in the older workers program should be terminated because of this action since normal attrition should accommodate the slot reductions. Also, increased funding for the dislocated worker initiative should provide a higher level of service to these workers. The reduction amount was not based on analysis, but rather is a budget number which, when combined with the Adult and dislocated worker programs' increases, will provide participation to a comparable number of persons aged 55 and older.

Question. You also propose a cut in Youth Training Grants under JTPA -- \$60 million, or 10 percent less. Why 10 percent instead of 13 percent or 7 percent?

Answer. Within the existing budget constraints, the Department has determined to expand its investment in new initiatives and programs which are considered effective and reduce investment in programs where there is evidence of limited impact.

The National JTPA study compared program outcomes for 20,000 Title II participants with a control group that had similar characteristics but who were not enrolled in JTPA. Sixteen local service delivery areas (SDAs) were included in the 30-month study which covered the period 1987 to 1989. The study concluded that "(t)here were no statistically significant positive effects on the earnings of (Title II-C) out-of-school youths, regardless of the service strategy for which they were recommended."

Based on the above findings, the Department requested a \$60 million (9.1%) reduction from the FY 1994 level for Title II-C. It was felt that the \$60 million reduction could be better utilized for new youth initiatives and programs of more proven effectiveness for youth. It was also felt that a reduction greater than \$60 million would seriously impair the In-school component of Title II-C, which the national study did not address. Even with the reduction, flexibility in shifting up to 10 percent of II-A and II-B resources to II-C will allow local areas to continue successful in-school programs at current levels. The reduction amount was not based on analysis, but rather is a budget number which, when combined with increases in other Youth programs, will provide a level of nearly \$3 billion for all youth programs in 1995, an increase of \$324 million above 1994.

CONSOLIDATION OF EMPLOYMENT PROGRAMS UNDER THE RE-EMPLOYMENT ACT

Question. I understand that the Administration proposes to consolidate a slew of employment programs. As I understand, this effort will make it easier for laid-off workers to find jobs and businesses to find workers. Such consolidation seems long overdue, and I would like to commend you for trying to rationalize the system. Can you tell me just a little about how we allowed so many programs to operate in the first place and how much easier it will be for a worker in a plant that closes to get a new job under your proposal?

Answer. In the past, a viable comprehensive program did not exist to address the displacement of workers regardless of the reason for their displacement. Many worker displacements resulted in legislation concerned with addressing a specific instance or category of dislocation. This, in turn, led to the proliferation of new, categorical employment and training programs which we are now addressing with the proposed Re-Employment Act. For instance, new programs have amended the Job Training Partnership Act (JTPA) as needs have arisen to address special target groups. These programs include the Defense Conversion Adjustment Program, the Defense Diversification Program, the Clean Air Employment Transition Assistance program. In addition, other programs to serve special groups of dislocated workers include the Trade Adjustment Assistance program for workers affected by trade-related dislocations and the Transitional Adjustment Assistance program for workers affected by NAFTA.

All of the programs cited above have separate funding streams and operating requirements which must be separately administered and complied with by the Department of Labor and State and local administering agencies. Under the proposed legislation, there will be one funding stream, a single set of eligibility criteria, and one set of operating and administrative requirements. This, of course, will reduce the administrative burden as well as make the system more customer-friendly. In addition, the Re-Employment Act authorizes the One-Stop Career Center system to provide universal access, by individuals and employers, to a comprehensive menu of quality employment, education and training information and services. This will enable an individual seeking a job to access information regarding a full array of services, including job openings, at one location.

ALTERNATIVE TO FUNDING THE RE-EMPLOYMENT ACT

Question. Your Re-Employment Act proposal looks like it may cost us a lot in the out-years, and several hundred million dollars in FY 1995. What happens if we are not able to come up with enough money to support such a fast expansion?

Answer. Estimates suggest that current dislocated worker programs serve only fifteen percent of the country's eligible dislocated workers. Due to resource constraints, grantees must restrict entry into these programs, and in some cases, limit the services provided to eligible individuals. Congress has appropriated \$1.118 billion for the FY 1994 Title III dislocated

worker program which significantly increases the total funding for dislocated worker programs beginning July 1, 1994, and allows us to serve an estimated 20 percent of dislocated workers. The Re-Employment Act is designed to serve 60 percent of the eligible population by the year 2000. We estimate that this is the percentage of eligibles who would avail themselves of our services.

The President's budget assumes a gradual ramp-up to full implementation for both system capacity and budgetary reasons. The outyear estimates have made room for this full \$13 billion 5 year cost within discretionary caps. If Congress does not appropriate the full request, then a smaller percentage of the eligible population will be served or the ramp-up to full implementation will take longer.

EMPLOYER MANDATES - HEALTH REFORM

Question. I would like to discuss Health Reform for a moment, and its effect on business and working people. Many tell me we need an employer mandate, yet many small businesses say they would go under if the Clinton bill passed -- even with its small business subsidies. Earlier this week, one of my colleagues in the House proposed exempting businesses with fewer than 10 employees from a mandate. Instead, they would apparently be required to pay a 1 or 2 percent payroll tax, depending on their size, and subsidies would be available to low-income people who work in small firms. Secretary Reich, do you think this may be the kind of proposal it is going to take to get us out of this bind? Do you think such a proposal could produce universal coverage while reducing the potential for job loss?

Answer. The Administration believes that our approach best produces universal coverage while reducing the potential for job loss. All firms will benefit from the President's plan, but small businesses have a special stake in health reform.

Today, the health care system is stacked against small businesses. Small businesses pay premiums up to 35% higher than large corporations for the same coverage. In addition, small businesses suffer from the worst aspects of the current insurance system, such as individual underwriting, occupational red-lining and age-rating.

The Administration's proposal would eliminate this nightmare. Regional alliances will give small businesses and their workers the bargaining clout to negotiate low priced health insurance. The proposal will eliminate the discriminatory insurance practices that can so dramatically increase the cost of health insurance for small businesses today.

For the majority of small businesses which still provide health insurance for their workers, the President's plan would achieve a substantial reduction in their labor costs. In addition, these businesses would compete on a level playing field, not on the basis of whether or not they provide health insurance. For small businesses that do not presently provide employee health care coverage, the President's plan would raise labor costs, but only moderately, based on a system of discounts that places substantial limits on these costs.

Under the President's plan, discounts are available for small businesses with average annual wages up to \$24,000 (about three times the minimum wage). The discount caps the cost of providing the standard benefit package at 3.5% of payroll for firms with fewer than 25 workers and average wages below \$12,000. This amounts to just 15 cents per hour for a minimum wage worker. The cap gradually increases to 5.3% for firms paying an average wage between \$15,000 and \$18,000 (twice the minimum wage) and 7.9% for those with average wages above \$24,000. Because they are calculated on average wages, the subsidies will lower the cost for many workers well above the minimum wage.

We think that workplace coverage is the best way for all workers to get health insurance. Experience has shown us that universal coverage achieved through the workplace is a proven formula for people and businesses. Hawaii's experience with workplace coverage has been impressive -- since it instituted workplace coverage in 1974, the unemployment rate is one of the lowest in the nation, small business creation rates have remained high, and the rate of business failures in Hawaii has remained less than half the national rate. In fact, the number of small employers in Hawaii grew almost 200% between 1970 and 1991.

HEALTH CARE REQUEST

Question. I understand that the Department of Labor has requested some discretionary funding increases for administrative costs related to enactment of the President's Health Care Reform Proposals. What I don't understand is that other affected agencies are not requesting similar increases. Do you know why Labor is and HHS agencies like the Public Health Service are not?

Answer. Within the Department of Labor, the Pension and Welfare Benefits Administration (PWBA) has current and ongoing responsibilities assuring that employer sponsored health plans are administered consistently with ERISA. Currently, we have significantly enhanced our enforcement efforts in health plan investigations, particularly involving Multiple Employer Welfare Arrangements (MEWAs). We expect that we will have an ongoing need for additional personnel to deal with investigative and advisory activities related to our increasing health enforcement responsibilities.

Under the President's health care reform proposal, the Department of Labor would be responsible for carrying out a variety of new enforcement, administrative, and regulatory functions. Because of the Department's limited in-house staff experience with the more technical aspects of health plan regulation and operation, expert consultants will be needed to assist in the development of many of the regulations and oversight activities that must be established. Additional FTE will be necessary to carry out a variety of the new administrative, regulatory, and enforcement functions.

However, the budget requested \$5.1 million for the Pension and Welfare Benefits Administration for health care reform on the assumption that the President's bill will be enacted this year.

This amount should have been included among the allowances for health security along with amounts for all other agencies that will have responsibilities in health care reform. The allowances appear at page 190 in Table 4-3, "Financing the Health Security Act" in the Budget of the United States Government, Fiscal Year 1995 and again near the end of Table 7-2, at pages 95-106, "Outlays by Function and Program" in the "Analytical Perspectives" volume. The separate request for the Department of Labor was an error.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

DEPARTMENT OF LABOR ROLE IN TEENAGE PREGNANCY PREVENTION

The most recent data on births among adolescents shows that the teen birth rate in 1991 continued the rise that began in the late 1980s. Between 1986 and 1991, the rate of births to teens aged 15 to 19 rose 24 percent, from 50.2 to 62.1 births per 1,000 females aged 15-19. Between 1985 and 1990, public costs related to teenage childbearing totaled \$120.3 billion according to the Centers for Disease Control and Prevention. Of this amount, \$48.2 billion could have been saved if childbearing had been postponed until the mother was age 20.

Question. Mr. Secretary, while I agree that the Department of Labor has an important role in fighting poverty and low educational achievement in high risk populations, is there not more that can be done by the Department to more directly impact upon reducing teen unwanted pregnancies?

Answer. Fighting poverty and low educational achievement in high-risk populations is the most direct way of reducing teen pregnancy and unwed parenting. Over 56 percent of teen mothers come from families with incomes of \$12,000 or less. Only 6 percent of women with a college degree become unwed mothers, as compared to 20 percent of women with a high school degree or less.

Question. Mr. Secretary, the cost to this nation of teenagers having children is enormous, costing over \$120 million between 1985 and 1990 for public assistance. As the Congress examines ways to overhaul the welfare system, what role should the Department of Labor have in reducing the number of teen births.

Answer. To fundamentally address the issue of teen parenthood will require a long-term strategy to end inner-city poverty. The Departments of Labor, Health and Human Services, Education, Housing and Urban Development, and Justice would all need to have a role in such a strategy. The Department of Labor's role in such a strategy would be to increase the long-term career opportunities for non-college bound males and females.

JOB TRAINING PROGRAM EDUCATION ON TEENAGE PREGNANCY

Question. Your letter states that the Department of Labor job training programs serve roughly 65,000 parents each year. Are these parents receiving information and training concerning responsible parenting and pregnancy prevention? If not, why not?

Answer. Some teen parents enrolled in JTPA are served as part of programs aimed specifically at this group. Young women served in such programs most likely are receiving pregnancy prevention and parenting classes. For example, Job Corps provides a wide range of family planning services to students including: pregnancy prevention methods, education, and counseling. The subject of pregnancy prevention is further covered in the health education curriculum which all students are required to take. All Job Corps students are required to take 20 hours of parenting education, which includes: basic parenting concepts, present and future roles as parents, how to provide a nurturing environment, child development and behavior, decision making, child safety and health, handling stress and controlling anger, and child neglect/abuse and how to get help. Other teen parents served in JTPA simply are enrolled in general job training programs (such as community college courses), and would not receive parenting and pregnancy prevention classes.

NEW CHANCE AND PARENTS FAIR CHANCE DEMONSTRATIONS

Question. Mr. Secretary, would you outline for the Subcommittee the New Chance and Parents Fair Chance demonstration programs? Would you support receiving additional funds to expand the number of demonstration programs in this area?

Answer. New Chance began in December 1988 and Parents' Fair Share in July of 1990. Both enjoy funding support from a variety of public and private sources. The overall cost of New Chance has been approximately \$11 million, with the DoL contribution at about \$2.75 million. The estimated total cost of the pilot phase to the Parents' Fair Share sponsoring partners is about \$6 million. DoL contributed \$200,000 to the endeavor.

The New Chance and Parents Fair Share demonstration programs both address welfare dependency and the plight of poor children. Both demonstration programs are targeted at families at-risk of long-term poverty and with children on AFDC. They have been funded by the Department of Health and Human Service, the Department of Labor, and various foundations.

The New Chance demonstration attempted to increase the employment, economic self-sufficiency, and general well-being of young women on AFDC who are high school dropouts, and to enhance the learning and development of their children as well. New Chance was piloted in five sites and currently operates in 16 sites in 10 States. Early results of a random assignment evaluation on the New Chance project will be coming out in about six weeks.

The Parents Fair Share demonstration served fathers of children on welfare who do not have custody of their children. It was tested in nine States with the goal of helping fathers get jobs, get involved with their children, and make child support payments. The Parents Fair Share demonstration is beginning a multi-year, multi-site random assignment evaluation.

The Department of Labor will consider funding based on an assessment of the outcomes from the current round of New Chance

and Parents Fair Share demonstration programs. As I have stated previously, programs that are proven to be ineffective will be decreased or eliminated while programs with proven effectiveness will be maintained or increased. The New Chance assessment is due in mid-summer of this year and the report on the pilot phase of Parents' Fair Share is due in early June.

JOB CORPS PREGNANCY PREVENTION PROGRAM

Question. Your letter states that the Job Corps program includes pregnancy prevention as part of its training. Could you explain what is being done? Has there been any evaluation of the elements of this program?

Answer. In an ongoing effort to discourage pregnancy among female students, Job Corps offers a wide range of family planning services to all program participants, including physical examinations, counseling, laboratory testing, birth control methods, and referral to community health centers if needed.

In addition to the clinical services mentioned above, pregnancy prevention is also promoted in several other required areas of training. As part of a thirty-eight hour curriculum on Health Education, it is specifically addressed in the module on "Reproductive Health". As an indirect approach, the subject of responsible decision making is addressed in both the Social Skills Training Program and the Parenting curriculum. The new Job Corps evaluation will look at the different rates of childbearing of the participant and control groups. Any differential found could be due to a combination of the vocational training provided, the residential experience, and the specific pregnancy prevention components.

Job Corps has not formally evaluated the elements of these programs. However, a one-time survey conducted in 1989 indicated that the pregnancy rate in Job Corps mirrored the National rate of 1 in 10 per year for the age group 16-21.

LIFE SKILLS TRAINING PROGRAMS

Question. Your letter also questions the "life skills" training programs which about 20 percent of the participants in the summer youth jobs program received. How long have these programs been in place? Over what period of time was the evaluation conducted?

Answer. The Summer Training and Education Program (STEP) was initiated in 1984 to test the effects of a "two-summer" remediation, work and life skills intervention on the lives of 14-15 year-olds from poor urban families who were already seriously behind academically. STEP provided youth with half-days of summer jobs under JTPA's Summer Youth Employment and Training Program, combined with half-days of remedial reading and math. One half-day each week was devoted to issues concerning decision-making and responsible sexual and social behavior.

Research (1984-1990), using a random assignment methodology on nearly 5,000 youth in five cities, showed that STEP's summer

effects were both positive and consistent - reading and math scores were 1/2 grade higher for STEP youth, and STEP youth had significantly higher scores on tests measuring knowledge about responsible social and sexual behavior. However, the positive summer impacts did not hold up once youth left STEP and returned to their regular school and life routines. A five-year follow-up of youth enrolled in STEP from 1984-1985 showed that STEP youth experienced the same dropout rate, college entrance, teenage pregnancy, and employment rates as the control group youth. Nevertheless, STEP is currently being replicated in over 150 sites throughout the country and continues to consistently demonstrate positive learning gains and increased knowledge in life skills among its participants.

The strength of STEP is its highly organized, intensive and controlled involvement in each youth's life during the summer. While providing positive summer experiences, however, short-term interventions like STEP do not fill critical gaps in the lives of disadvantaged young people where the conditions of poverty present major obstacles to intervention.

PRISON EDUCATION AND JOB TRAINING PROGRAMS

Prison Population Statistics: There are approximately 1.3 million persons incarcerated in prisons, jails, and juvenile facilities in this nation. Only 40 percent of prison inmates and 45 percent of prisoners in jails have graduated from high school, and most have few, if any, job skills. It is my belief that criminal offenders, especially the juvenile and first and second offenders, should be given a chance at rehabilitation and gainful employment.

Office of Correctional Job Training and Placement: Last year, I offered an amendment to the Crime bill which would create within the Department of Justice, an Office of Correctional Job Training and Placement. This office would coordinate correctional job training and placement programs for adults and youth within the Departments of Labor and Justice to assist state and local offices, and prepare training materials for State and local agencies to equip staff with the skills needed to assist incarcerated persons in gaining marketable occupational skills and job placement. I originally proposed locating this Office within the Department of Labor. However, the Administration opposed locating the Office within the Department of Labor.

Question. Mr. Secretary, I have a long standing concern regarding the attention given to prison education and job placement programs. If we are going to significantly reduce the recidivism rate, we must provide gainful employment opportunities to help ex-offenders readjust in society. Within your Department, Secretary Reich, can you identify any program which will address the job placement issue?

Answer. Per the 1992 JTPA Reform Amendments, both the JTPA Adult and the Out-of-School component of the Youth Training Grants programs target offenders as one group of hard-to-serve individuals. As such, the Amendments require that not less than 65 percent of the participants in these programs shall be members

of all such defined hard-to-serve populations. In addition, the Department of Labor currently runs the Federal Bonding Program. This program gives employers of ex-offenders a special fidelity bond providing insurance that protects the employer against employee dishonesty. The insurance policy is issued through the AETNA Casualty and Surety Company and is paid for by the U.S. Department of Labor. The bonding is provided free of charge to the employer for a period of up to one year. The job placement must be for full-time work - 30 hours or more per week. (This definition of full-time employment has been in use since the late 1960s - derived from the U.S. Employment Service standard used for the purpose of qualification for Job Training stipends. Its use is intended to allow a greater number of ex-offenders to be bonded who otherwise would not qualify for this service and hence, not gain employment.) with reasonable expectation of job permanence. Over 15 years, this modest-sized program has had a 98.5 percent success rate. It is currently funded at \$250,000 a year and serves roughly 1,500 persons each year.

Also, the Administration's Youth Employment and Skills (YES) initiative will provide critical job opportunities for disadvantaged youth and young adults in selected high crime, high unemployment neighborhoods in an effort to reduce crime. YES will use a saturation approach that directly provides youth with jobs in the targeted neighborhoods regardless of income. The emphasis will be on private sector jobs but public sector jobs will be provided where necessary. The goal is to incorporate a full-fledged employment approach into a range of services and to change the opportunities and expectations of neighborhood youth and young adults to one of gainful employment in the private sector, thereby providing an incentive to avoid crime.

Key program design features include:

- Tying participation to good behavior, such as avoiding crime and drugs, and returning to school; and
- Leveraging of other programs and resources through a public/private partnership, as well as obtaining matching commitments from the community.

A maximum of 10 grants will be awarded, at a planned authorization of \$525 million, in order to ensure a neighborhood saturation of jobs for all youth in the targeted area. Finally, a rigorous national evaluation of the program will be conducted assessing the program's effectiveness of: reducing crime, enhancing employment and earnings, promoting entrepreneurship, reducing drop-out rates, and increasing educational attainment.

TRAINING FOR JTPA PROVIDERS REGARDING EX-OFFENDERS

Question. I understand that between 7 to 9 percent of participants in JTPA adult job training programs are ex-offenders. Have providers of JTPA services received training in dealing with the special needs of this population?

Answer. Given the decentralized nature of JTPA, we do not know whether these service providers have received specific

training in dealing with the needs of ex-offenders. To do their jobs effectively, counselors, job developers, trainers and others in the JTPA system must have an understanding of the unique needs of the various population groups, such as ex-offenders, which we serve. We believe that generally JTPA staff who work with these individuals are dedicated to their work and knowledgeable of the special needs of these persons and the services they require to become self sufficient. As you know, one of the goals of our capacity building activities in JTPA is to increase the professionalism and effectiveness of the front line staff. We believe that this effort will result in staff who will do an even better job in serving disadvantaged people.

NEW YOUTH EMPLOYMENT AND SKILLS CRIME PREVENTION DEMONSTRATION

Question. I understand that the Crime Bill reported by the House Judiciary Committee includes authorization for a new Youth Employment and Skills Crime Prevention Demonstration Program that you had proposed. Would you describe this proposal for the Subcommittee? Why did you wait until now to bring this proposal to the attention of the Congress? Do you need separate authority to undertake this demonstration program or can it be done within the demonstration authority under Title IV of JTPA?

Answer. This proposed demonstration has been developed in consultation with several Departments, including HUD, DOJ and DOL. The coordination between the Departments took time in order to develop the Administration's position. In inner-city neighborhoods with high crime rates, the employment rate for young out-of-school males is disastrously low - perhaps 40 percent. This demonstration will attempt to saturate selected neighborhoods with employment and training programs in any effort to boost employment rates of young males to a level comparable to that found in more advantaged neighborhoods. Through such a saturation, we hope over a five-year period to change community-wide expectations and norms regarding work, family, and crime. To achieve such a saturation, we will need to conduct the demonstration in small neighborhoods rather than entire cities. We expect to conduct the demonstration in six to ten neighborhoods at a five-year cost of \$525 million.

The demonstration is being put forward to Congress now because it is generally recognized that the Crime Bill will be strengthened if there is more balance between preventative and punitive measures. The Department of Labor would need separate funding under the authority of the Crime Bill to conduct this demonstration or additional funding authorized under JTPA Title IV demonstration authority.

OFFICE OF CORRECTIONAL JOB TRAINING AND PLACEMENT

Question. Last year, I offered an amendment to the Crime bill which would create an Office of Correctional Job Training and Placement within the Department of Justice. This office would coordinate Labor and Justice Department Correctional Job Training programs for adults and youth. Mr. Secretary, my original

amendment located this office within the Department of Labor. However, due to your Department's reported opposition, the amendment was redrafted to locate the office within the Justice Department. Since your Department has the most experience with job training programs, would it not make more sense for the office to be located at the Department of Labor?

Answer. An office is one way to address this need, although other coordination mechanisms are also feasible, especially in this era of streamlining Federal organizations. If this office is established in the Department of Justice we will work closely with this organization on its coordination responsibilities.

EX-OFFENDER TRAINING PROGRAMS EVALUATION

Question. Has the Department of Labor done an evaluation of training accomplishments and employment outcomes for ex-offenders who were served by Job Training Partnership Act employment and training programs?

Answer. During PY 1991, 52,000 ex-offenders were served by JTPA Title II, representing almost 10 percent of all persons served. Roughly 36,300 of these were 21 years of age or older, and 15,700 were under age 21. The Department of Labor has evaluated JTPA Title II in a major study in which program applicants were randomly assigned to treatment and control groups. The study found that JTPA was effective in serving adults, but we did not have information on offender status for adults. The study did, however, collect information on the prior arrest rates of youth. The study found that JTPA was not effective in serving youth, regardless of whether they had a prior arrest record or not.

A similar random assignment study was conducted by MDRC of the JOBSTART demonstration - a fairly intensive non-residential program that provided both basic education and job training to dropout youth. The MDRC study found that the program was not particularly effective in serving youth without prior arrest records, but was quite effective in raising the earnings of youth who entered the program with prior arrest records.

TAMPERING WITH COAL DUST SAMPLES

Question. I chaired a hearing of the Subcommittee on August 1, 1991 to explore allegations of widespread tampering by mine operators with coal dust samples. These samples are taken to measure the levels of respirable coal dust in the nation's underground mines. On April 4, 1991 the Secretary of Labor announced the issuance of over 4,700 citations to over 500 coal companies. Mr. Secretary, would you update the Subcommittee on the outcome of the Mine Safety and Health Administration's investigation into coal operators tampering with coal dust samples?

Answer. MSHA's investigation revealed that widespread deliberate tampering of respirable dust samples had occurred. This is especially evidenced by successful criminal convictions and the dramatic drop in the incidence of altered samples, even though

the Agency continues to uncover fraudulent dust sampling activities. From October 22, 1993 through March 14, 1994, only four samples out of the nearly 30,000 submitted by mine operators and weighed and opened by MSHA have been found with irregularities. The result is an altered samples' incident rate of approximately 0.01 percent compared to 10 percent prior to announcement of the problem.

Question. Where are we in the litigation process?

Answer. Litigation continues for both criminal prosecutions and civil penalties. The mine operators have contested the majority of the citations issued and civil penalties assessed for dust sample tampering contending that irregularities in samples could result from actions other than deliberate tampering. An administrative law judge ruled in the "common issues trial" that the existence of an "abnormal white center" alone on the sample filter surface does not conclusively prove that the sample was subjected to tampering. Accordingly, the parties have begun the process of conducting hearings on the specific samples cited at each mining operation. The first such hearing was concluded in January and a final decision is expected by the end of April.

Question. Have any criminal convictions been obtained?

Answer. There have been 137 guilty pleas and convictions (54 companies and 83 individuals) entered for dust-related fraud.

Question. What long-term action has been taken to ensure this tampering does not occur in the future?

Answer. MSHA is working with all members of the coal mining industry to address what long-term action should be taken to ensure this tampering does not occur in the future. For example, MSHA has strengthened its enforcement program and its oversight of the operator sampling program and will revise the dust regulations. In addition to examining all operator submitted samples for irregularities, MSHA verifies compliance with dust standards during regular inspections and during sampling and monitoring activities. Problem mines are targeted for extra attention through special health enforcement activities. Revising the dust regulations will enhance the integrity of the operator's sampling program, provide for monitoring of dust exposures under more representative operating conditions, improve the quality and effectiveness of dust control plans, and strengthen the dust sampling certification process.

Technological improvements will also help ensure against future problems. More tamper-resistant cassettes, which recently became commercially available, now account for over 85 percent of those used in the operators' sampling program. A new sampling pump with the capability to indicate if it was shut off during sampling is undergoing field testing. MSHA has recently entered into an agreement with the Bureau of Mines for the development of a continuous dust monitor.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

DISLOCATED TIMBER AND SALMON WORKER RETRAINING

Question. Earlier this month Oregon submitted a grant application for \$8.8 million under the Department's Title III discretionary account for the President's Northwest Economic Adjustment Initiative. I understand Oregon would like to begin delivering services on April 1. Has the Department made a decision on the funding of this application? If not, when do you expect a decision? Will the Department abide by its guideline of 30 to 40 days for the review and approval of grant applications?

Answer. Oregon's Timber 9 application for \$8.8 million was received by the Department of Labor on March 8, 1993. The Secretary announced a grant award of \$5,035,275 to assist 840 dislocated timber workers on April 1, 24 days after the application was received. The Department is attempting to process all grant applications within 45 days of their receipt.

TIMBER INITIATIVE SET-ASIDE

Question. Is the \$12 million set aside for the President's Option 9 Timber Initiative a ceiling, or a floor? Did applications coming into the Department by Oregon, Washington and California prior to program year 1993 (7/1/93 - 6/30/94) count against the Timber Initiative commitment?

Answer. The President's Timber Initiative reserves \$12 million a year for meritorious proposals from California, Oregon, and Washington to assist workers adversely affected by reduced timber harvests in the Pacific Northwest and northern California. The funds are reserved from July 1 through March 31 each year, and any grant application received on or before March 31 will be considered against the set aside. Requests received and grants funded prior to July 1, 1993 are not counted against the Program Year 1993 reserve. Should the affected states submit applications in excess of the reserved \$12 million, the Department will consider those requests in the same manner it reviews all requests. Thus, it is possible that the Department could provide assistance above the \$12 million.

TIMBER INITIATIVE WAIVERS

Question. Under the President's Timber Initiative, the Northwest delegations were led to believe that Federal agencies would be willing to waive barriers that cause excessive delays or restrict the delivery of needed services to the targeted populations. I understand Oregon's grant application requests waivers of the eligibility requirements for Needs-Related Payments and waiving the 25 percent cost limitation for support services. Mr. Secretary, will the Department uphold the commitment of the President to extend to states the necessary waivers and procedural flexibility?

Answer. The Department does not have the authority to waive statutory restrictions or prohibitions. Nonetheless, we successfully worked with the States to fund programs designed to

meet the needs of the affected workers. This includes provisions to allow Needs-Related payments for each worker who was participating in a retraining program to find a new job. Under the Re-Employment Act, many of these restrictions will be eliminated and there will be waiver authority to waive other restrictions to provide the most flexibility.

MIGRANT AND SEASONAL FARMWORKER RETRAINING

Question. Mr. Secretary, what is the justification for the \$7 million cut in the Migrant and Seasonal Farmworker program?

Answer. The Department is requesting the same appropriation level in fiscal year 1995 for the Migrant and Seasonal Farmworker program that it requested for fiscal year 1994, which meets the statutory set-aside requirement. We believe this level to be adequate for this program, particularly during times of tight budgetary constraints.

MIGRANT AND SEASONAL FARMWORKER EVALUATION

Question. Has the Department undertaken an evaluation of the 402 program? What were the results?

Answer. Yes. An evaluation of the Migrant and Seasonal Farmworker Program (the "402" program) was conducted from June 1991 through June 1993. It studied the effects of different service strategies, e.g., agricultural upgrade, basic skills and non-agricultural occupational training, and other support and training services, on migrant and seasonal farmworkers participating in the 402 program. The study found that many programs were effectively serving migrant and seasonal farmworkers and that many programs had effectively adapted their service delivery to the needs of the eligible populations in their areas. The study also found that the quality of program services was uneven and made recommendations for improvements by the program grantees.

Major study recommendations were to:

- Focus more on the hard-to-serve, including specialized recruitment techniques, and use the supportive-services only component as a recruitment device.
- Better tailor basic skills, vocational and on-the-job training for the specific needs of participants.
- Give programs more freedom to respond to fluctuating needs by provide increased flexibility, emphasis on migrants, and reducing documentation of clients in the supportive-services only cost category. Clients need sufficient financial support during training to maintain themselves.
- Upgrade and increase bilingual staff.
- Expand technical assistance efforts, including further clarification regarding employability enhancements, performance standards, and transferring client eligibility across programs.

PERCENT SERVED MIGRANT AND SEASONAL FARMWORKER PROGRAM

Question. What percentage of the eligible population is the program serving?

Answer. Based on the 1980 Census count of approximately 400,000 migrant and seasonal farmworkers and the approximately 1 million Special Agricultural Workers, a category created by the Immigration Reform and Control Act of 1986, a total of 1.4 million are eligible for the program, of which approximately 3% are being served. An average of 50,000 farmworkers are served each year by the program.

MIGRANT AND SEASONAL FARMWORKER PROGRAM AS PART OF CONSOLIDATION

Question. As you know, I am inclined to support proposals to consolidate the myriad of job training programs across federal agencies. However, due to the very special needs of migrant farmworkers, I am concerned that consolidation is not an effective strategy for farmworkers. What is your view on this issue?

Answer. My overall view is that to achieve administrative efficiencies and to improve program effectiveness, a general consolidation of the scores of job training programs must be realized. The domestic and world economy is rapidly changing to the point where only those nations with highly skilled and efficient work forces will prosper, and within those work forces, only those with competitive skills will have hope of advancing their individual economic status. My view is that to achieve these objectives, we need an overall national strategy which addresses the training needs of all our citizens who need them, including the hardest to serve such as migrant and seasonal farmworkers.

 QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

NEW JOB CORPS CENTER SITE SELECTION

Mr. Secretary, when you were before the Subcommittee last May, I inquired of you as to the status of the Department's consideration of applications for new Job Corps Centers. Several communities in Mississippi were under consideration at that time as possible sites. I am advised that the Department, on March 10, 1994, made its decision and selected 9 sites for construction of new Job Corps Centers. Although no Mississippi sites were chosen, I understand that Prentiss, Mississippi was a finalist.

Question. Will the applications from communities such as Prentiss that were finalists in the previous competition remain eligible for selection as one of the 6 new sites that you have requested funding for in FY 1995, or will new applications be required?

Answer. It is our intention to invite all interested communities to submit a proposed site for location of a Job Corps center, assuming Congress approves our proposed expansion. The

invitation will be published in the Federal Register and will include specific criteria for evaluating proposals. Communities that submitted proposals previously, but were not selected, will be encouraged to revise and/or re-submit proposals.

JOB CORPS HELP WITH DEFICIENT APPLICATIONS

Question. Will the Department work with these finalists to help them identify and correct deficiencies in their applications?

Answer. The Director of Job Corps, in his letter to all finalists communities whose sites were not selected, offered specific feedback on the evaluation of individual proposals to interested proposers, either in person or by telephone. Several communities have requested and received a briefing. In addition, we have referred interested communities to our Job Corps regional offices to assist proposers with their continued interest and to answer questions.

JOB CORPS SITE SELECTION CRITERIA FOR FY 1995

Question. Will the process for selection of the 6 centers requested in FY 95 be carried out in the same manner as the last round, or are there any changes contemplated?

Answer. At this time, we anticipate that the same or a similar process will be utilized for the selection of sites for the six new centers.

REEMPLOYMENT ACT CONSOLIDATED PROGRAMS AND COST

Mr. Secretary, I understand the Administration has recently proposed a "Reemployment Act" that would consolidate several programs that now serve dislocated workers.

Question. What are the 6 programs that are to be consolidated into the new "Reemployment Program" and what will be the cost of this new consolidated program over the next few fiscal years?

Answer. The six programs are: Economic Dislocation and Worker Adjustment Assistance (EDWAA) program; Trade Adjustment Assistance (TAA) program; NAFTA Transitional Adjustment Assistance program; Defense Conversion Adjustment (DCA) program; Clean Air Employment Transition Assistance (CAETA) program; and the Defense Diversification Program (DDP). In addition to program consolidation, assistance to all dislocated workers will be expanded and improved under the proposed Re-Employment Act.

The projected costs are:

PY 1995	- \$1.465 billion
PY 1996	- \$2.222 billion
PY 1997	- \$2.576 billion
PY 1998	- \$2.651 billion
PY 1999	- \$2.994 billion
PY 2000	- \$3.366 billion

RE-EMPLOYMENT ACT COST COMPARISON TO EXISTING PROGRAMS

Question. How will its cost compare with the sum of the costs of the existing programs projected over the same period?

Answer. The current availability for these programs is \$1.5 billion. \$1.7 billion is requested for all dislocated worker programs in 1995. The Re-Employment Act program is designed to significantly increase services to the population of dislocated workers. The current mix of programs is serving only 15% of the population of dislocated workers. The new Re-Employment Act program is designed to serve 60% of the eligible population by the year 2000.

To achieve this, significant investments will be made in the quality of services which are available to dislocated workers. The consolidation of targeted programs into a single comprehensive program will produce increased operating efficiencies in the delivery of services and may result in reductions in duplicative administrative functions.

The program requirement, through early worker profiling, that UI claimants who are dislocated workers participate in reemployment services as a condition of receiving UI benefits is expected to reduce the period of unemployment, and the amount of paid-out UI benefits, for such workers.

PERSONNEL TO ADMINISTER THE RE-EMPLOYMENT ACT

Question. In this time of reinventing government, we are seeking ways to eliminate bureaucracy and the inefficiency that it entails. Will the new "Reemployment Program" result in more or fewer personnel to administer the consolidated programs?

Answer. In the long-run, "savings" will result from the efficiencies inherent in consolidating dislocated worker programs and integrating job training services under One-Stop Career Centers. It is important to note, however, that these "savings" are likely to take the form of more accessible and higher quality services for customers - and not necessarily result in a reduction in the staffing or other resource requirements of the job training and employment system.

Today, job transitions are more frequent, more permanent, and more likely to be associated with the need for skill enhancement. This describes an economy that is radically different from the one that prevailed when our current employment and training system was developed. The Re-Employment Act of 1994 (REA) will provide American workers with the information and job skills they need for success in this new economy.

Successful reemployment programs in today's economy need to be highly responsive to customers' needs, connected to state-of-the-art labor market information, and provide services whose quality persuades all persons to use them. We believe that we can deliver services of this type with improved efficiency under the REA and indeed, are committed to do so. Thus we plan to take advantage of the economies and efficiencies achieved through consolidation to provide improved quality and level of services.

NUMBER OF CONSOLIDATED PROGRAMS IN THE RE-EMPLOYMENT ACT

Question. Why is your proposal limited to the six dislocated worker programs? Wouldn't a more comprehensive approach to our problems of worker training and retraining necessitate that we look at the entire range of employment and training programs?

Answer. Our proposal consolidates all Federal programs for dislocated workers. Also, for States that decide to establish One-Stop Career Centers, the REA provides for waivers of statutes and regulations that are barriers to better integration of job training and labor market information services for all persons.

We believe that program consolidation and waivers to achieve integration services for programs that are not consolidated are the basic building blocks for reform of the job training and employment system. Through the REA, we have taken the first critical step toward reform of the Federal job training and employment system. When enacted, the REA will offer important learning opportunities with respect to the impact of consolidation and waivers on achieving our goal - high quality and highly responsive customer service. We are studying options for future program consolidation.

Question. I'm advised that there are over 150 programs that could be considered for consolidation and/or revision. Can we anticipate that the Administration will submit a more comprehensive proposal in the future that would address the duplication and overlap in these programs?

Answer. Our current proposal consolidates all Federal programs for dislocated workers. Further consolidation takes time and may prove difficult. The Administration has decided to start with an achievable, incremental approach rather than attempting wholesale consolidations at the outset. We, therefore, are studying options for future program consolidation.

SCHOOL-TO-WORK OPPORTUNITIES - COORDINATION WITH STATES

Mr. Secretary, last year when you were before the Subcommittee, you described the then new School-to-Work program which was to be jointly funded by the Departments of Labor and Education. I raised with you the fact that Education leadership at the state level in Mississippi were considering a similar state based program to assist in the transition from secondary school to the workplace.

Question. Has the Department been able to work with States that have undertaken their own school to work programs?

Answer. States and localities that have undertaken school to work activities were extensively consulted during the development of the Administration's proposed School-to-Work Opportunities Act. In fact, practitioners from across the country met with us and shared their experiences in operating Youth Apprenticeship, Tech Prep, Career Academies, Cooperative Education and other programs and offered their counsel for developing a nationwide system that goes beyond any single program. The proposed legislation is the product of these discussions.

The Departments' implementation strategy and the success of this initiative depends in large part on the work of these same states and localities. It is recognized that not all states are prepared to undertake the broad-scale change envisioned by the proposed legislation, nor are there sufficient funds to immediately finance them even if they were prepared to begin implementation. Thus, the plan is to identify leading edge states through a competitive process and to make significant investments to enable them to pioneer the way for others. Each year additional states will then be added to begin implementation. These later states will benefit from increased development time and lessons learned from states that preceded them.

DISTRIBUTION OF SCHOOL-TO-WORK FUNDS

Question. How will the \$300 million request for FY 95 be distributed to the local school to work programs?

Answer. They will be awarded on a competitive basis. At the local level, the School-to-Work Opportunities initiative brings together local partnerships of employers, educators, labor organizations, and other local community and business leaders to build high quality school-to-work programs that prepare young people for careers in high-skill, high-wage jobs. There are two ways for these local partnerships to participate in the School-to-Work Opportunities initiative:

- On a limited basis, through the direct Department of Education/Department of Labor grants; and
- Ultimately, through statewide systems.

Approximately two-thirds of the total funding in FY 1995 will be provided to local partnerships to implement this initiative. This includes an estimated \$22 million for Federal Implementation Grants to Local Partnerships. These competitively awarded grants will provide direct funding to a relatively small number of localities that are ready to implement School-to-Work Opportunities programs. An additional \$30 million is set-aside for Grants to Local Partnerships in High Poverty Areas. These grants, also competitively awarded, will finance implementation of School-to-Work Opportunities programs in high poverty areas of urban and rural communities.

Most of the \$300 million requested will be used for competitively awarded State Implementation grants. These grants will go to those States that can demonstrate substantial ability to begin full-scale operations and implement the statewide School-to-Work Opportunities plan. Under the proposed legislation, grantees must award at least 65% of the funds provided to local partnerships during the first year of the grant. Thereafter, the percentage awarded to local partnerships will increase each year.

Those States not receiving implementation grants may continue to receive smaller State Development Grants. These grants provide resources to States to plan and create comprehensive statewide School-to-Work Opportunities systems. We expect that States will use a portion of these available funds to support local School-to-Work Opportunities planning and development activities and to initiate pilot programs for testing key elements of program design.

STATE AND LOCAL DISCRETION IN SCHOOL-TO-WORK PROGRAM DESIGN

Question. How much flexibility will there be for the state and local officials in terms of designing programs to help in the school-to-work transition?

Answer. The proposed legislation provides for a substantial degree of flexibility and experimentation so that programs can address local needs. However, all State systems and individual local programs will share a set of common features and core basic components. This is not intended to limit local flexibility but is intended to ensure a national framework within which all States can create statewide School-to-Work Opportunities systems.

 QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

THE WOMEN IN APPRENTICESHIP AND NONTRADITIONAL OCCUPATIONS ACT

This small program enacted in 1992 provides technical assistance to employers and unions to assist them in successfully placing women in apprenticeships and nontraditional jobs and to prevent sexual harassment on the workplace. Carpentry, painting, and welding are examples of apprenticeship occupations; electronic technicians, mechanics, and maintenance engineers are considered nontraditional jobs in which 25 percent or less of the workplace is female.

This program is vital to opening opportunities for women in apprenticeships and nontraditional jobs. Places such as Everett Community College, the Displaced Homemakers Center at Lake Washington VTI, the Apprenticeship and Nontraditional Employment for Women (ANEW) in Renton, FOCUS in Seattle, the Seattle Office for Women's Rights, and the Women's Employment Network in Seattle and Vancouver are all eligible for these funds, and should be commended for their leadership in extending more opportunities to women in the workplace.

Question. I am pleased that the President requested last year's funding of \$750,000 for the Women in Apprenticeship program. How would you measure its success in its first year? Do you think this program deserves additional resources?

Answer. An InterAgency Agreement between the Bureau of Apprenticeship and Training (BAT) and the Women's Bureau will enable both agencies to jointly administer the Women in Apprenticeship and Nontraditional Occupations Act, P.L. 102-530. The purpose of the Act is to encourage employers and labor unions to expand the employment of women in apprenticeable and nontraditional occupations.

The InterAgency agreement is a collaborative effort, designed to implement the technical assistance grant provisions of the Act and its related provisions. Specific objectives include:

- Providing grants to community-based organizations to deliver technical assistance to employers and labor

unions to prepare them to recruit, train, and employ women in apprenticeable occupations and nontraditional occupations.

- Building on recent studies, research and programs to examine the barriers to the participation of women in apprenticeable and nontraditional occupations and developing recommendations to reduce such barriers.

The project aims to increase the number of women in apprenticeship and nontraditional occupations and address the employment barriers of women.

We will not be able to measure the project's success or estimate the number of participants or projects until the grants are awarded in September, 1994. We expect to award 5 to 10 grants to community-based organizations, which are expected to provide technical assistance to 50 employers and unions.

JOB CORPS SITE SELECTION

The Job Corps has a proud tradition of providing beneficial training to disadvantaged young Washingtonians between the ages of 16 and 21. It provides youths basic education, vocational training, job placement, medical support, and other services in a residential setting. However, the percentage of the population of eligible enrollees served, 1.57 percent, is well below other States in the Northwest region. For the past two years the City of Seattle has developed plans for a new Job Corps Center to address the desperate need for urban youths in Washington State. The city expects to compete this year for start-up funds.

Question. I am delighted with the President's request to increase Job Corps by \$100 million. Will the Department of Labor welcome innovative urban-based designs for new Job Corps sites? Is there a bias towards the more traditional rural setting for Job Corps sites?

Answer. The Department is very much interested in innovative designs for new Job Corps sites, whether rural or urban-based. There is no bias toward locating Job Corps centers at rural sites. For example, only one of the nine selections in the 1994 selection process, Loring AFB in Caribou Maine, is considered as a rural site. Job Corps also has the advantage of recruiting both eligible urban and rural students for any center, regardless of its location.

GLASS CEILING COMMISSION REPORT

Question. During consideration of last year's appropriation bill, language was included at my request stating that:

"The Committee is concerned that a final report expected last March (1993) will not be available until the end of 1994. Therefore, the Committee directs the Glass Ceiling Commission to issue its report within three months of enactment of this appropriation bill."

In a letter to the Committee on November 24, 1993, you stated that in the interest of the planning, research, and public

education necessary to complete this report, that the report would not be ready by January 1994 as requested by the Committee. You state in your budget justification that:

"In the interest of reaching a broad base of organizations, employers and individuals concerned with this issue, as required by statute, it is expected that the final report will be issued in January 1995."

Mr. Secretary, that is not acceptable to those of us concerned with this issue. While we were pleased to receive the interim report of the Glass Ceiling Commission issued in August 1992 and entitled "Pipelines of Progress - A Status Report on the Glass Ceiling", we have seen nothing since.

What is the status of the Glass Ceiling Commission's research and investigation for the report?

Answer. The Commission has concentrated on collecting and analyzing existing data and research pertaining to the advancement of minorities and women into management and executive positions in the private sector. In addition to the areas delineated in the legislation, the Commission is studying differences and similarities of barriers and opportunities for white women and men and women of different racial/ethnic groups; determining whether there are barriers to advancement which are common to both the "sticky floor" and the executive suite; examining the impacts of federal employment legislation and enforcement, of family friendly policies, and of restructuring and downsizing on the presence and advancement of minorities and women in management and decision-making positions; and exploring the costs and benefits (the bottom line) to private employers of diversity and glass ceiling initiatives.

The Commission anticipates beginning to draft the final report within the next two months. The final report is expected to be submitted to the president and the Congress by January 1995.

Question. Is the Commission prepared to submit an additional interim report if Congress directs it to do so?

Answer. Such a report would be submitted if so directed. However, the preparation of an interim report will divert the activity of the Commission from some of its planned efforts, and result in a slight delay in the issuance of the final report. It should be noted that "Pipelines of Progress - A Status Report on the Glass Ceiling" was not a product of the Commission.

Following the change of administrations, a new Executive Director, Joyce Miller, was appointed in May 1993. Since then, the Commission has focussed on three areas: planning, public education, and research. Summarized below are the Commission's efforts in these three areas.

In the planning activity, to date there have been four Commission meetings, most recently in February 1994 in Los Angeles, and three public hearings. At the Commission meetings, a mission statement and a plan of work were developed and extensive discussions focussed on research projects and the final report.

The objective of the public hearings is to solicit information and recommendations on successful strategies for breaking the glass ceiling. Further Commission meetings and public hearings are scheduled in Cleveland in April, in New York in June, and in Atlanta during the summer. A Commission research sub-committee has met three times and will report to the full Commission at the April meeting.

The Commission has developed the criteria for the Frances Perkins-Elizabeth Hanford Dole Award and is now in the planning stages of the design of the medal, the award ceremony itself, and the selection of the recipient.

In the area of public education, as already indicated, there have been four Commission meetings and three public hearings. In addition, in cooperation with Commission Members, the Commission is conducting forums and roundtables with small groups to discuss the various issues which contribute to the glass ceiling and strategies for breaking those barriers. These forums and roundtables have been held in New York, San Antonio, Chicago, Los Angeles, San Francisco, and Boston. The Chicago roundtable was on "Women in Construction," and was attended by contractors, unions, and minority women.

The Executive Director has spoken to many groups around the United States as well as Finland, Japan, and Australia; has met personally with Congressional Commission Members Senator Paul Coverdale, Senator Patty Murray, and Representative Nita Lowey to discuss Commission activities and progress; and has testified before the House Small Business Committee, chaired by Congressman John LaFalce. If you wish, please have your staff notify me so that I can arrange a meeting between you and Ms. Miller to discuss the Commission's progress. Commission members have joined the Executive Director in addressing groups across the country about glass ceiling issues and the work of the Commission. Additional forums will be held around the country during the remainder of 1994 and the Commission regularly receives recommendations from academicians, representatives from organizations, employers, and others who are concerned with glass ceiling issues.

The Commission has also developed and published an informational pamphlet which defines the term "glass ceiling" and explains the role of the Commission. A total of 110,000 copies were printed and approximately 80,000 have already been distributed. In addition, many interviews have been held with both U.S. and international visitors. There has been a great deal of press coverage of all these activities. To ensure that the Commission members are kept current on glass ceiling issues, they are sent press articles and other relevant information on a bi-monthly basis.

In the area of research, prior to the appointment of Ms. Miller in May 1993 as Executive Director, the Commission had undertaken no research. Since then, seventeen (17) short-term research contracts have been awarded for comprehensive reviews and analyses of existing research and data examining a wide spectrum of glass ceiling related issues. Among the issues targeted are race, ethnic and gender-earning equality; the impact of recruitment, promotion, selection and compensation policies;

family friendly policies; successful initiatives in breaking the glass ceiling; barriers to workplace advancement experienced by women, African Americans, Hispanics, Asians, Native Americans, persons with disabilities, and persons in low paying occupations; the impact of education on upward mobility; and examination of the glass ceiling in the professions. An eighteenth study has been commissioned on the impact of corporate restructuring and downsizing on the glass ceiling. Eight (8) of these studies have been completed and two (2) more are in final stages. All of the research being undertaken as a part of the Commission's work was initiated after the appointment of Ms. Miller as Executive Director.

ACTIONS BY THE DEPARTMENT AGAINST WASHINGTON STATE AUTO DEALERS

Recently, in Washington state, the Department of Labor has taken actions against the auto dealers over the use of lot attendants.

On February 4, of this year, I received a letter from the Washington Auto Dealers Association detailing the problems they are facing with the DOL. For your convenience I will provide you with a copy of WADA's letter.

As part of what is apparently termed a "Strike Force" operation, the DOL sent surveys to dealers in Washington in December of 1993 asking them for the names, addresses, and phone numbers of minors who have worked for them in the past two years. DOL then contacted the employees and former employees of those dealers and asked them about the nature of their jobs. Based on the information gathered as a result of the good faith compliance of the businesses to the Department's requests, the dealers received notices of violation for violating child labor regulations and recently has sent out letters of assessment. The letters of assessment were sent to 59 auto dealers and total \$200,000 in fines were issued. Fines are running as high as \$10,000 per dealer.

At the heart of this controversy is not some gross violation of minors' rights or a even clear violation of the law. The businesses were fined for allowing workers who were under 18 years of age and who had valid state drivers licenses to drive automobiles. The problem arises out of the Department's interpretation of the use of the words "incidental and occasional" in the DOL statutes. Under the "Hazardous Occupations Orders in Non Agricultural Occupations; Motor Vehicle Occupations" section of the DOL regulations, it states that driving by minors shall be "occasional and incidental to the child's employment." However, nowhere in the DOL regulations or in letters to employers has the Department defined "occasional and incidental." Further, there is no case law on this issue from which to discern a definitions, because the provisions have apparently never been enforced.

The auto dealers were aware of occasional and incidental language and were, to be best of their ability, trying to comply. As you can guess, without a clear definition to follow it can be a very difficult task.

The result of the Department's actions has been very dramatic. According to the WADA, at least 500 jobs will be lost because dealers will simply cannot afford to risk punitive action by the DOL for trying to provide employment opportunities to persons under 18 years of age.

In response to the actions taken by the Department, on March 9, the Washington State Congressional delegation sent a letter to you asking you to evaluate this situation and to specifically provide a definition of these undefined terms. I will provide you with a copy of the letter.

While I am supportive of the Department's efforts to enforce federal labor laws, I am concerned about the effects these latest actions have had on jobs and economic opportunities for youth in Washington state and the repercussions it could have across the nation.

Question. What is the status of your reply to this letter?

Answer. A response will be forthcoming very soon.

Question. Do you take the position that persons under 18 years of age who hold valid state drivers licenses and have taken state approved driver's instructional courses should not be allowed to drive on public roads and highways?

Answer. Under the Fair Labor Standards Act, since 1941, regulations issued by the Department have banned the employment of 16 - and 17-year olds from working as drivers. The issue in this case is not whether persons under 18 years of age should be licensed and allowed to drive on public roads and highways; rather, it is whether minors under 18 should be permitted to work in occupations that have been determined to be hazardous, such as motor vehicle operations.

The large number of traffic accidents in the United States, many involving personal injuries or fatalities, certainly indicates that driving remains a dangerous activity. Statistics also show that many accidents happen close to home or on short trips. Finally, as evidenced by higher insurance rates, the accident rates for youthful and inexperienced drivers under age 25 are higher than the accident rate for all other drivers.

Question. If this is not your position, are you willing to reevaluate the child labor regulations to focus on employability of youth rather than on punishing employers who provide employment opportunities for youth?

Answer. We believe that there are some occupations that are inherently dangerous and should remain prohibited for minors under 18 years of age. At the same time, we fully support initiatives to enhance the training and employability of youths and are working hard to ensure the success of these initiatives, including through enhancing the school-to-work transition process for non-college bound youths. Our dual responsibilities must complement each other given their equal importance to our society. We must seek a balance between adequately protecting young workers and

assuring the continued availability of job opportunities so important to their future.

In this context, we are initiating a rulemaking process to reexamine and obtain public input on the current child labor regulations, including the adequacy and appropriateness of the hazardous occupations orders. We will certainly look at this fundamental issue through that process.

Question. What is your official interpretation of what constitutes "occasional and incidental" driving?

Answer. Under the existing hazardous occupation order (HO2), the operation of motor vehicles is prohibited for workers under 18 years of age, however, there is a limited exception for driving that is "incidental and occasional." While those terms are not defined in the regulations, numerous opinion letters over the years have stated that this exception applies to rare or emergency situations and not where driving is a regular part of the young person's job. The Washington car dealer investigations found that the young workers were expected to drive cars between lots and dealers, return customers to public transportation, drive to gas stations, etc. as a normal part of their duties-- clear violations of the regulations.

Question. Have violations of this provision been enforced in the past or in other parts of the nation? If so, will you provide me with information on those enforcement actions?

Answer. Between FY 1989 and FY 1993 we conducted more than 50 investigations where HO 2 violations resulted in serious injury, disability or death to minors. These investigations were conducted throughout the nation. Investigations of HO 2 violations in which injury, disability or death was not present were also conducted throughout the nation.

Question. What was the basis for initiating these actions against the dealers in Washington state? Was there an abnormal increase in complaints filed with the Department or an increase in the number of traffic accidents involving youth who were working for an auto dealer in the Puget Sound area?

Answer. The Department announced a stepped-up child labor education and enforcement program in 1990. Since then, there have been an ongoing series of initiatives to seek higher compliance with child labor laws and educate the public about the requirements of the regulations.

The investigations in Washington were planned and executed as part of Wage and Hour's regional child labor initiatives for Fiscal Year 1994. For the past several years, these initiatives have generally been aimed at industries where significant numbers of minors are employed and violations of the child labor laws, especially hazardous occupations order violations that could result in serious injury or death, are likely. This child labor enforcement initiative in Washington State was based on exploratory investigations which revealed a high frequency of violations by auto dealers and justified an expanded program to cut these violations.

Question. Is it your priority to ensure future compliance of employers who were acting in good faith based on the best interpretations of vague regulations and not to merely punish them with thousands of dollars of fines?

Answer. Wage and Hour's first priority is to establish full compliance. We do so through a balance of education and outreach, investigation programs intended to identify and remedy violations, and mechanisms intended to deter violations, such as publicizing our enforcement efforts and results and through civil and, where warranted, criminal penalties.

With regard to the Washington State auto dealers, our Wage and Hour Regional Administrator has met with the Washington State dealers association to discuss the application of the law and agreed to work with the dealers to achieve compliance with the child labor provisions.

Wage and Hour Administrator Maria Echaveste has written to the National Automobile Dealers Association and the American International Automobile Dealers Association asking them to publicize information on the application of the laws.

We are committed to working with the industry in the hope that they will be of substantial assistance in achieving full compliance.

Question. How can I work with you to clear up this situation in Washington state? Can these concerns be alleviated through regulatory changes or does it require legislative action?

Answer. We appreciate your interest and willingness to assist in resolving this issue. Because the concerns of the Washington State automobile dealers involve strictly regulatory issues, legislative action would not be necessary in this case.

With respect to possible regulatory changes, we are initiating an Advance Notice of Proposed Rule Making (ANPRM) that will provide the public, including the Washington automobile dealers, an opportunity to suggest child labor regulation changes. We certainly urge the dealers to participate in that process and present any data that they may have to support the view that driving should not be considered a hazardous occupation for minors under 18.

QUESTIONS SUBMITTED BY SENATOR CONNIE MACK

USE OF INCREASED RESOURCES FOR WAGE AND HOUR ENFORCEMENT

Question. The President's budget increases the Employment Standards Administration by \$17 million dollars. Again, I have concerns about this increase and what the money will be used for, especially if this funding is being used to distort the intent of the Fair Labor Standards Act (FLSA). Let me give you an example:

The City of Vero Beach, Florida was fined \$2,000 under FLSA for employing children after 7 p.m. They had a young cheerleading coach work beyond 7 p.m. when there was a night football game and

they paid junior staffers of the recreation department for the 15 minutes they spent waiting for parents to pick up their children after 7 p.m. Vero Beach was able to negotiate the fine down to \$400.

That city was doing their part to employ young people in good jobs, that promote self-esteem, and the Department of Labor goes out and fines them.

Can you explain why you need this increase?

Answer. While I can't speak to the specific case you cite, it is a violation of the Federal child labor regulations to employ youngsters under 16 years of age past 7 p.m. except during the summer months when school is not in session (when there is a 9 p.m. limit). We are proceeding with a rulemaking action to solicit public input on changes that may be appropriate in these regulations, including both these hours limitations and the hazardous occupations orders which restrict dangerous employment of young people under 18 years of age.

With regard to your more general question, the President's budget reflects a program increase of \$3,807,000 for the Wage and Hour Division. The additional funds requested for Wage and Hour will be used for: (1) 23 FTE and \$700,000 in support of enforcement initiatives directed at low wage industries and egregious violators, (2) \$356,000 for training to improve the skills, productivity and effectiveness of all staff; (3) \$540,000 for enforcement travel, and; (4) \$2,211,000 for information systems development in support of Wage and Hours' enforcement program, reinvention and restructuring efforts with primary emphasis placed on full automation of Wage and Hour's front-line investigative staff.

IMPORTANCE OF WORKER SAFETY

Question. Your budget provides for an \$18 million increase to pay 132 extra FTE's in the worker safety and health area. To me, this must mean that OSHA is understaffed and needs help dealing with its workload. Recognizing the importance of worker safety, I have some concerns about this increase and let me tell you why.

FIRST EXAMPLE:

-- Until recently, acts of heroism could get you fined. When a trench collapsed on 21 year-old Dwight Kaufman in Boise, Idaho, two of his co-workers jumped into the tory to save him, without regard for their own safety. OSHA fined the company \$7,875 because these good samaritans failed to put on their hard hats.

-- Fortunately, we passed an amendment to S. 4 that allows for such heroic acts without fear of fines from overzealous OSHA Inspectors.

SECOND EXAMPLE:

-- A small silk screening business in Florida was recently visited by an OSHA inspector. The inspector informed the business owner that he was there to perform a "routine" OSHA inspection.

-- OSHA informed the owner that he was in violation of the **Hazard Communications Standards regulations** because he failed to maintain a current **Material Safety Data Sheet** on a bottle of "hazardous material."

-- To his utter astonishment, the owner was informed the "hazardous material" in question was a bottle of Joy dishwashing liquid next to the sink. OSHA told him that he needed to provide instructions to his staff on the safe use of the dishwashing liquid. Furthermore, he was found to be in violation of Federal regulations because the bottle of dishwashing liquid did not have a safety warning label affixed to it which read "DO NOT DRINK."

Can you explain to me what duties these additional FTE's will perform?

Answer. The FY 1995 budget request for an additional \$18 million and 132 FTE constitutes increases for OSHA and the Office of the Solicitor to enhance the enforcement of the nation's occupational safety and health laws. The request represents the importance this Administration places on the health and welfare of American workers.

The majority of the requested positions are dedicated to front-line activity, the inspection of worksites and any attendant litigation against those who fail to comply with their responsibilities to ensure worker safety and health. The remaining new positions are devoted to developing safety and health standards, training safety and health professionals, and enhancing available injury and illness data so that the Department can target its activities at those employers and workplaces that have poor safety and health histories.

We note with concern the examples that were provided about OSHA inspections. As cited, such instances are clearly aberrations and do not reflect agency policy. We are making every effort to remain sensitive to the concerns of both employers and employees as we carry out our regulatory responsibilities, including worksite inspections. Isolated examples of purported poor judgment should not undermine this request or the positive impact it will have in furthering protection for American workers.

CREATION OF THE OFFICE OF THE CHIEF ECONOMIST

Question. I understand that a new office was created in the Labor Department last year with a budget of half a million dollars. My understanding is that one of its major purposes is to analyze and provide labor statistics - much as the BLS does - directly to the Secretary of Labor. Can you tell me why this office is necessary since the BLS already performs this role? Please provide me with copies of the reports and other output this office has produced over the year. How much funding are you requesting for this office this year?

Answer. The Office of the Chief Economist was established to serve as the primary economic advisor to the Secretary of Labor and to provide economic analysis of general labor market developments, current Labor Department programs and new initiatives under consideration by the Administration. The staff in this office provide direct advice to the Secretary and represent the Secretary in high level and sensitive dealings

bearing on current economic issues, initiatives and proposals under consideration by the Administration and the Congress. The office conducts economic appraisals of new initiatives under consideration by the Department of Labor and of existing Departmental activities; and it also performs ad hoc analyses of broader economic issues. These duties are quite distinct from the development, collection and analysis of labor statistics performed by the Bureau of Labor Statistics.

Over the past year, the Office of the Chief Economist has regularly provided the Secretary with economic advice on and analyses of a wide range of issues including: the determinants of changes in the U.S. wage structure over the last two decades; the overall economic effects of the North American Free Trade Agreement and its impacts on immigration into the United States; the effectiveness of government training and education programs; the effectiveness of reemployment services including job search assistance, reemployment bonuses and self-employment assistance; changes in the scope and nature of worker dislocation and unemployment; and the impacts of high-performance workplace practices on firm performance. Copies of these reports are being provided under separate cover.

A total of \$535,000 is requested to support the work of this office in fiscal year 1995.

BUREAUCRACY UNDER THE "HEALTH SECURITY ACT"

Let's look at a family of four -- Dad has a full-time job, Mom has two part-time jobs, the older daughter is away at college, and the young son has a part-time job after school. That's four employers for this family. Under the Clinton plan, no employer or combination of employers for a family would have to pay more than 80% of the premium. Please explain how this will work:

Question. What are the reporting requirements for each employer? To whom do they provide the information?

Answer. An employer is required to contribute to premiums and report information only for individuals who are "qualifying employees." If a young worker is under age 18, or a full-time student under the age of 24, and is his or her parents' dependent, he is not a "qualifying employee." A part-time worker who works fewer than 40 hours per month at a particular job is not a "qualifying employee" of that employer. Thus, it is likely that in the case of this family, the son's employer and one or both of Mom's employers will not be required to contribute premiums or report information for them.

In the case of qualifying employees, employers must report annually, for each employee, the total number of months that the employee worked full-time and part-time, and the total amount deducted from wages and paid for the employee's family share of the premium. Employers also report the total employer premium payments made for all qualifying employees for the year (and, if the employer is subject to a premium discount, the total premium payment the employer would owe without the discount) and the number of full-time qualifying employees and the number of part-time qualifying employees for the year. This information must be reported to

regional clearance centers, which will be established by the National Health Board to serve as an information clearinghouse.

On a monthly basis, employers will be required to pay premiums and account to the regional alliance for the total number of qualifying employees working full-time and part-time, the number of hours employees in each category work, the employer premium contributions made for each employee, and the employee's health insurance policy status. Employers also will report the identity of each individual employed or terminated during the month (unless they are not "qualifying employees"), the individual's regional alliance, and the individual's class of family enrollment.

Question. How long do they have to maintain the records?

Answer. This is not specified by President's proposal.

Question. Are they required to provide it to employees?

Answer. Employers are not required to provide this information to employees. However they must, on an annual basis, provide to any individual who was a qualifying employee during any month the following information: the individual's total number of months as a full time and/or as a part-time employee, the individual's wages (while a qualified employee), and the total amount deducted from their wages and paid for the family share of their premium.

Question. Who determines if the combination of employer contributions is more than 80%?

Answer. Under the Clinton plan, for a qualifying employee with family coverage, each employer pays 80% of an "adjusted premium" for a qualifying full-time employee (working at least 120 hours per month). The employer pays a pro-rata share for a qualifying part-time employee (working between 40 and 120 hours per month).

The adjusted premium is determined by the regional alliance. It is based on the average number of workers per family for the regional alliance. Of course, some families may have more workers than the average, and other families may have fewer. These balance out such that employer contributions within a regional alliance for all families together are 80% of the weighted average premiums for families.

By using this flat per-worker premium system, we have removed one of the greatest sources of complexity and unfairness in the current system: coordinating and tracking premiums, payments, and coverage for families with multiple workers.

Question. Do alliances have the authority to audit small business owners' records?

Answer. Yes. Each regional alliance employer must maintain records and provide information to the regional alliance as necessary for verification and audit of the reported information.

Question. Do alliances have to give notice to the small business owners that an audit is forthcoming?

Answer. This is not specified under the President's plan.

Question. Will small business owners be able to have CPA's present at audits?

Answer. This is not specified under the President's plan.

Question. Are small business owners responsible for paying CPA's to attend audits?

Answer. This is not specified under the President's plan.

Question. If an error is made, will there be interest and penalty charges?

Answer. Regional alliances will use credit and collection procedures, including the imposition of interest charges and late fees for failure to make timely payment, as necessary.

Question. What appeal rights do small business owners have if they disagree with alliance auditors?

Answer. This is not specified under the President's plan.

Question. These reporting requirements are on top of other unfunded mandates and paperwork requirements from OSHA, EPA, IRS, Social Security Administration, and a myriad of state and local departments and agencies. At what point do we say "enough"?

Answer. Our health system is in desperate need of reform, and the President's bottom line is guaranteed private insurance for all Americans. We think that workplace coverage is the best way to get this coverage, because it preserves and builds on our employer-based system. It makes no sense to scrap a system that works well for most people and start over.

To be effective, any health reform plan would require some enforcement mechanism. We feel that an employer-based system provides an efficient enforcement mechanism, in part because employers already comply with a variety of other benefit withholding requirements, such as for Social Security. In addition, there are only 5 million employers, where there are 220 million non-elderly persons who would have to be tracked under a plan which did not provide for employer withholding and reporting. Such a system would be more administratively complex and harder to enforce. As a result, the enforcing agencies would have ever expanding resource needs, which would result in ever larger appropriations requests.

PART-TIME WORKERS

Question. What research has been performed to determine the effect an employer mandate will have on the ability to create part-time jobs?

Answer. There is considerable research in the labor economics literature on the relationship between cost increases and employment. The most analogous of this work to health care reform are studies of the effects of minimum wage increases on the demand

for labor. The most recent work in this area indicates that minimum wage increases have had a negligible employment impact. Some recent analyses have concluded that these increases were associated with higher levels of employment.

The Administration has not specifically undertaken a study to determine the effects of its proposal on part time jobs. The more general employment literature supports the Administration's position that while health care reform may have a variety of impacts in the labor market, overall these will be largely offsetting and result in a minimal net impact on employment.

Question. I've talked with employers of both large and small businesses who have told me they will be forced to eliminate part-time jobs. Yesterday, I was told by one employer that instead of paying for two part-time workers and doubling the exposure in terms of health care costs, the company would simply hire one full-time worker.

I have received letters from small business owners throughout Florida about the impact of an employer mandate on small business.

"The employer mandate would force me to reduce staff to manage cash flow. My two part-time employees would lose their jobs. Let me tell you about one of these part-times. Jeanne is 73 years old. She's bright, active and puts in 20 hours a week. She needs the extra income to supplement her Social Security income. If I'm forced to pay for her health care, she will lose her job."

From the workers' standpoint, this is another economic roadblock to economic freedom. After all, they are subject to the Social Security earnings test, the recently passed Social Security Benefits tax hike, capital gains taxes on investments and the like. Why should we punish older workers who seek to supplement their incomes?

Answer. Older individuals who work part-time will not be punished by the Clinton plan. They will receive the same guaranteed comprehensive benefit package as other workers, with the same premiums as those other workers. And they will pay roughly the same amount for these benefits as they would have paid for coverage under Medicare Part B.

Employers may find the cost of covering the older worker to be lower than expected. In the case of a part-time worker employed more than 40 hours a month, the employer pays a portion of the employer's share of the premium for a full-time employee. In Jeanne's case, the employer would pay about 54% of her premium. (If the employer was eligible for discounts, it might pay a smaller share.) Because the Clinton plan requires insurers to community rate premiums and prohibits rating based on the worker's age, the premium of an older worker, such as Jeanne, would be no higher than the premium of any other part-time worker. If the employer currently provides health care for other employees, the substantial savings realized by the employer may mean that the employer's total health care costs, even with the cost of covering the older worker, will be reduced.

In general, as the non-partisan CBO has stated, "The Clinton plan... would not significantly slow the economy or result in the loss of jobs, as many critics have charged." Comprehensive health care reform is a necessary element in a strategy to increase long-term economic growth, reduce the deficit, and create new jobs. In fact, two independent studies, one from the Economic Policy Institute and one from the Employee Benefit Research Institute, predict that jobs will be created as a result of health reform.

PURCHASING POOLS

Question. Under the Clinton plan, most small businesses would be forced into alliances. What's wrong with permitting small businesses to simply pool their resources to form their own health alliances and avoid having to write checks to a government pool over which they have no control?

Answer. The Clinton plan requires all small and mid-sized employers (with up to 5000 employees) to join a regional alliance to create a sizable pool; undoubtedly this pool would be larger than any health alliance voluntarily created by small firms in the same area. The size of this pool is crucial to making it possible for insurers to offer low-cost community-rated premiums. The larger the pool, the greater the employers' joint employers negotiating strength will be, and the better able it will be to spread risk.

The regional alliances will not be government controlled pools; on the contrary, they will be operated by the consumers and employers whose interests they protect. The states have a great deal of flexibility in the creation of regional alliances: they can be nonprofit organizations, public corporations or state agencies. Regardless of the form the regional alliances take, the governing board will be made up of equal numbers of employers and consumers.

Question. Can many small businesses pool to the point that they have 5000 in their pool and they opt-out of the mandated alliance participation? Why not?

Answer. The Clinton Plan does not permit small businesses to group their employees to reach 5,000 employees in the aggregate to opt-out of mandated alliance participation and form a multiple employer welfare arrangement, or MEWA. MEWAs have been eliminated because, frankly, they have created the kinds of problems in our health system that cry out for reform.

Under current law, a significant number of MEWAs have, over the past several years, created tremendous problems for participants, employers, state regulators and the Department of Labor. These abusive and fraudulent MEWAs have bilked participants and employers out of hundreds of millions of dollars in premiums and unpaid claims. Moreover, states and the federal government have devoted vast resources and time to investigating, indicting, and prosecuting unscrupulous or fraudulent MEWA promoters and operators without significant success in recovering claims for participants.

We believe that by eliminating MEWAs and creating regional alliances, we can preserve the best aspects of the MEWA-type structure (i.e., pooling small and medium-sized employers together

for purchasing power and community rating), while preventing the fraud and abuse perpetrated by many MEWA operators today.

We believe that the ability to form a corporate alliance generally should be limited to those with a strong employment based relationship. The union-negotiated multiemployer health plans and the rural telephone and electric cooperative health plans are excepted from the regional alliance requirement because they have unique characteristics that make them suitable to be part of the reformed health system. Union plans, when negotiated pursuant to a collective bargaining agreement, offer greater reliability and accountability than MEWAs. Rural telephone and electric cooperatives, because they have developed a way in which to successfully cover rural populations, are performing an important service that should not be dismantled. Moreover, union plans and rural cooperatives, should they elect to continue under the Clinton Plan, will be required to meet the federal standards for corporate alliances, standards which most MEWAs could not meet.

The following questions relate to the Administration's health care proposal. There is currently no subsidy to firms with wages below \$24,000. In the Administration's proposal, it should be noted that there is no direct subsidy to low wage firms; rather, the proposed provision provides for an insurance premium rate reduction to such low wage firms as a means to limit the negative cost impact of the proposal on small businesses.

CAP ON HEALTHCARE COSTS

Question. Small business subsidies are available to firms with average wages of below \$24,000. Two weeks ago, however, the Labor Department reported that wages and benefits increased by only 0.6% after inflation. Doesn't this approach encourage lower wages?

Answer. The cap on healthcare costs as a percentage of payroll will not keep workers' wages down; indeed, wages and job mobility are likely to be enhanced under the Clinton plan.

The employer cap will not keep wages down. Wages rise gradually. As they approach the cap (7.9%) and pass the point where the cap applies, the cost differential to the employer will be very small. An employer who tries to keep wages down simply to reduce health care costs by a relatively small amount will be faced with a potentially serious labor relations problem, and if the problem persists, an employer will probably begin to lose good employees to competing businesses. The forces of the labor market will not allow employers to artificially keep wages down.

The Clinton plan also facilitates worker mobility, which provides opportunities for increased wages. A common problem today is "job lock"--the inability or unwillingness of workers to change jobs because of fear of losing health insurance coverage for some period of time. By assuring every American continuous coverage, "job lock" is eliminated, providing workers with more flexibility to pursue new job opportunities and higher wages in the job market.

Finally, controlling the increase in health care costs frees resources for other purposes. The forces of the labor market will

result in some of these resources going to workers in the form of higher wages.

SMALL BUSINESS SUBSIDIES

Question. How does this approach jibe with the Administration's rhetoric about a high-wage, high-skilled economy? The subsidies would be going to many old technology firms. To me, the better approach would be to also provide the subsidy to high-tech, high-salary small businesses.

Answer. The goal of Administration policy is to encourage the development of worker skills and other policies which will promote and support high-wage jobs. The small business subsidies is a recognition of the economic reality that small, low-wage firms may not be able to pay the full cost of health insurance. The subsidies will minimize the loss of low-wage jobs in these firms.

Indeed, the Administration's overall proposal is inherently pro-growth and therefore could lead to higher wages among workers in many industries and firm sizes.

1. For businesses of all sizes, the controlling of health care cost inflation will represent an enormous savings. Money that would otherwise have gone to health care costs will be available for other purposes, including new investment and higher wages.

2. The controlling of health care costs will make exporting businesses more competitive. U.S. firms pay a higher cost for health care than comparable businesses in any of our major trading partners.

3. There will be greater equity among businesses. The current system results in significant cost-shifting between firms that provide health insurance benefits to their employees and those firms that do not. Under the reform system, firms will be competing based on the quality of their products and services, not the ability to shift health care costs to their competitors.

4. Many small businesses will benefit from reform. Currently, 62% of employees of small businesses are offered health insurance. The cost of insurance for small businesses in today's market can be very high. Under reform, community rating and the pooling and purchasing power of the regional alliances will significantly lower the cost of good health insurance for small businesses.

5. The administration proposal may spur entrepreneurship. Under the current system, the high cost of insurance (and for some, the total inability to purchase insurance because of preexisting conditions) may deter many people from trying to start their business. Individuals may be willing to take the risks inherent in business entrepreneurship, but they may not be willing to put their or their families' health at risk, too. Under the administration's proposal, such individuals would still be guaranteed access to the comprehensive benefit plan at affordable prices.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you very much. The subcommittee will stand in recess to reconvene at 9:30 a.m., Friday, May 13, when we will meet in room SD-192 to hear from Charles C. Masten, inspector general, Department of Labor.

[Whereupon, at 11:55 a.m., Thursday, March 24, the subcommittee was recessed, to reconvene at 9:30 a.m., Friday, May 13.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1995

FRIDAY, MAY 13, 1994

**U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.**

The subcommittee met at 9:34 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Byrd, Harkin, Reid, and Bond.

DEPARTMENT OF LABOR

OFFICE OF INSPECTOR GENERAL

STATEMENT OF CHARLES C. MASTEN, INSPECTOR GENERAL

ACCOMPANIED BY GERALD W. PETERSON, ASSISTANT INSPECTOR GENERAL, OFFICE OF AUDIT

OPENING REMARKS OF SENATOR HARKIN

Senator HARKIN. The Senate Appropriations Subcommittee on Labor, Health, Human Services, and Education will come to order.

This morning, we will hear from each of the three inspectors general whose job it is to eliminate fraud, waste, and abuse in their respective Cabinet agencies: the Department of Labor, Department of Education, and the Department of Health and Human Services. We have also asked the Commissioner of the Social Security Administration to testify on the matters being addressed by the health and human services inspector general.

This is not a traditional budget hearing. Each inspector general is asked to submit for the printed committee hearing record a prepared statement justifying fiscal 1995 budget requests. Today's testimony will focus on specific issues highlighting waste, fraud, and abuse. I believe the members of the public will find this discussion informative and valuable. But before we get to these issues let me provide just a brief overview.

The agencies under the jurisdiction of this subcommittee receive \$259 billion in direct appropriations for fiscal year 1994, and in addition spend another \$476 billion directly from trust funds such as Social Security, Medicare, and unemployment compensation. This subcommittee has the responsibility to ensure that these funds are wisely and efficiently spent.

When I learn of situations of fraud, waste, and abuse and unnecessary duplication in our programs I intend to make every effort to eliminate them. The hearing today will enable us to do that, and that is why for the past 3 years I have convened these special oversight hearings for the inspectors general. So this is the third year that we have done this now.

We will begin with Labor Department Inspector General Charles Masten, who will focus on excessive and improper cost being billed to the Government by grantees and contractors for overhead expenses. Then we will hear from Inspector General James Thomas for the Department of Education on Schools' failure to pay refunds on loans made under the Federal Student Financial Aid Programs. Finally, we have a panel consisting of Deputy Inspector General Mike Mangano and Social Security Commissioner Shirley Chater focusing on abuses in the Supplemental Security Income Program such as those involving drug addiction and alcoholics.

At this point, I would leave the record open for any statements by the ranking member, Senator Specter, and I would yield to my good friend from Nevada, Senator Reid, for any opening statements he has.

OPENING STATEMENT OF SENATOR HARRY REID

Senator REID. Chairman Harkin, I am very happy that you are holding this hearing, which is, as you have indicated, a series of hearings you have held over the last several years. I think there is nothing more important for us to do than to do away with the fraud and abuse that exists in the system. Health care alone, with the increased costs that we will have this year, if we could eliminate the fraud and abuse it would be a \$100 billion a year savings right there.

Now, we all realize we cannot eliminate it all, but certainly, we have got to eliminate part of it. If we eliminated half of it that would be \$50 billion. It is significant. We have, in the Aging Committee, done a little bit of work on the Social Security disability SSI cash benefits to drug addicts and alcoholics. I am not going to be able to stay for the entire hearing. I wanted to come here and spend some time this morning to indicate the support that I feel you should have as chairman of this subcommittee, and I want to again underline and underscore my appreciation for your doing this hearing and these others that you have in the past on this subject.

Senator HARKIN. Thank you very much, Senator Reid, and I want to publicly thank you for your involvement in this and your help and your support, and that of your staff also. As you pointed out, we may not get it all, but if we get some we are saving the taxpayers a lot of money. It is the kind of thing where you cannot just do it once and you are done because it just keeps popping up year after year.

Senator REID. Senator Harkin, it is like the gambling industry which is so heavily involved in Nevada. The commodity there is cash, so you plug one hole and they will come and dig another hole. They never stop. And that is the same here. There are such large sums of money involved that we have to be vigilant. We have not been vigilant enough, quite frankly.

If they were stealing this kind of money from the savings and loan or some other financial institution we would be up in arms. But here, we are talking about \$100 billion a year. And we are not concerned nearly enough.

Senator HARKIN. Thank you very much, Senator Reid.
Senator Bond.

OPENING STATEMENT OF SENATOR CHRISTOPHER S. BOND

Senator BOND. Thank you very much, Mr. Chairman, for calling this hearing. I, too, am very much concerned that the SSI program is going the way of AFDC and that the general public soon is going to view it as a synonym for Government spending on waste and inappropriate recipients. There are many SSI who are truly needy, and we need to focus on them. But there is a great deal of both anecdotal and documented evidence that on the street the program is perceived as one that provides generous benefits and it is one on which you can easily gain the system.

I had a letter I wanted to share with you, some of the comments from the principal of the New Haven Accelerated Elementary School in Columbia, MO. She says:

First, let me assure you that there is no greater advocate for children than I. I have been a Missouri educator for 30 years, a principal for 13. I want kids who need help to have it. However, the system is being ripped off and schools are expected to spend time, money, and effort to send records.

She cites a couple of examples:

We have a little boy who had been labeled learning disabled while in the early childhood program. He was then placed in a regular kindergarten class and did so well he has been tested and dismissed from special education. He no longer carries a label. His parents, while he was in the learning disabled category, applied and received SSI benefits for him.

She goes on to state:

I am sure he is still getting them, as the person from the Department of Education I talked to told that cases were supposed to be reviewed every 2 years but rarely was anybody taken off benefits. We have a case from which I have removed the child's name. He is in a regular classroom doing as well as most, but because he is on Ritalin I guess the mother thinks he should have Social Security supplemental income.

We have parents of preschoolers trying to get doctors to say their children are attention deficit so that they can qualify. It is not at all unusual for us to get requests for information even before the child has been tested.

Now, that is the end of her quote. But I would go on and say the last thing in the world Government should be doing is providing an incentive for parents to put their preschoolers on a drug like Ritalin so that they will be eligible for a cash payment. But there are evidences that are indications this may be happening and a terrible waste of money. And cases like this will undermine public confidence in the program so that the truly needy will end up suffering blame and stigma.

So Mr. Chairman, I look forward to not only this hearing but to following up to see what more we can learn in this area.

Senator HARKIN. Thank you very much, Senator Bond.

SUMMARY STATEMENT OF HON. CHARLES MASTEN

Now, we will call our first witness, Labor Department Inspector General Charles Masten. Last year, you gave us an excellent presentation of your work uncovering fraud and abuse in multiple-employer health and welfare insurance schemes, and from my review of your written testimony for today's hearing your presentation will be most informative. We will include your entire prepared statement in the hearing record, but due to our limited time if you would please summarize it we would be most appreciative.

Mr. Masten.

INDIRECT COST ABUSES

Mr. MASTEN. Thank you. Good morning Chairman Harkin and subcommittee members. Thank you for inviting me to testify before you in my capacity as inspector general of the United States Department of Labor on the issue of indirect cost abuses by grantees and contractors. This morning I am accompanied by Gerald W. Peterson who is the Assistant Inspector General for the Office of Audit. From the onset I would like to emphasize that the views expressed today by me are mine as inspector general and may not be the official views of the U.S. Department of Labor.

Mr. Chairman, by way of background, when Federal agencies award grants and contracts, the Government agrees to be responsible for the Agency share of grantees' or contractors' total indirect costs that are used to administer the specific grant or contract. If a grantee or contractor submits unallowable expenses as part of its indirect costs, it can result in the Government paying a higher share of the indirect costs than it should.

Government rules specify that contractors and grantees may only claim costs, both direct and indirect costs, that are allowable, allocable to the contract or grant activity, and reasonable and necessary in the conduct of the contract or grant. Despite these requirements, Mr. Chairman, OIG audits continue to identify substantial unallowable costs. Reviews by GAO, HHS, and other Federal agencies have yielded similar results. As a result, I see improper charges to grants and contracts, particularly indirect costs, as a growing widespread problem that potentially affects all Government agencies.

By way of illustration, Mr. Chairman, my office just issued three audit reports questioning over \$3.6 million of total incurred indirect costs claimed by a Job Corps support contractor. DOL's share of the questioned indirect cost is \$622,575. Mr. Chairman, listed on table 1 are some of the items that we questioned because these costs were personal in nature and incurred by the company's president or on his behalf. That is the first chart to my right, giving an indication of personal indirect costs that we think are unallowable and totally inappropriate.

Senator HARKIN. This is one contractor?

Mr. MASTEN. Yes.

Senator HARKIN. And these were?

UNALLOWABLE INDIRECT COSTS

Mr. MASTEN. That is an example of some of the unallowable indirect costs that we questioned.

Senator HARKIN. Let me understand this. The grant went out for whatever it was—I do not know what the grant was for—and then later on when they submitted—what, their bills?

Mr. MASTEN. When they submitted their total indirect costs for the 3-year period, they reported a total of \$26.2 million in total indirect costs. And the share that gets allocated to the Department of Labor, as indicated by the other chart, is \$7.75 million. Listed on the very first chart are some of the costs that we questioned: the personal expenses, the personal residence expenditures, the Tokyo office.

Senator REID. Is there some secret who the contractor is?

Senator HARKIN. I do not know. Is this public? I do not know.

Mr. MASTEN. I believe the audit has not been resolved, Mr. Chairman. Until it is resolved I would not like to name this contractor. DOL is not continuing to do business with them at this time.

Senator HARKIN. I guess what I do not understand is that the grant went out, then later on they put in these claims. How did you find out, for example, that \$275,000 was listed as entertainment. Is that what they listed themselves?

Mr. MASTEN. They listed this as part of their indirect cost as it related to the project, several items totaling that amount. When we go in and audit, we go through their documents and see exactly what the money was spent for. That total is just a broad overview of the expenses. The specific details are even more ridiculous than the totals listed on the chart.

Senator HARKIN. So the details are even more ridiculous?

Mr. MASTEN. Yes.

Senator HARKIN. In what way?

Mr. MASTEN. For example, we talk about \$70,000 in liquor, some of those liquor bills include bottles of wine that cost \$280 a piece and a bill from a vendor for \$34,000 for seven deliveries of wine.

INTEREST AND PENALTIES

Senator REID. How would they ever think they could get away with something like this?

Mr. MASTEN. As I continue to summarize my testimony, I can only tell you that this is a way of doing business by some contractors. That is one of the reasons we are advocating that Congress give us the same authority to impose interest and penalties that DOD has so that we can put somewhat of a deterrent in place to stop this.

Senator REID. There is no deterrent now?

Mr. MASTEN. No.

Senator HARKIN. All right.

Mr. MASTEN. Mr. Chairman, if you do not mind, I'd like Mr. Peterson—

Mr. PETERSON. I might add for a minute that even when they are caught, even in this particular case, in large measure they get away with it because all that will happen to them is that DOL will

not allow that particular cost. However, they have had the money for years. So, even when you catch them, since there is not a penalty that can be imposed, the most that can happen is they will have to reimburse that which DOL had already paid. In effect, therefore, they have had an interest free advance from the Government in many cases for 4, 5, or 6 years.

So when you say how did they think they could get away with it, even when we catch this type of thing—they get away with it.

Senator REID. Plus their drinking and clean clothes.

Mr. MASTEN. And going to real nice social clubs.

Senator HARKIN. All right. I do not understand the second chart. I guess you are getting to that, though, right?

Mr. MASTEN. Right. The total indirect costs that were submitted by this particular contractor totaled \$26.2 million, and of that amount we reviewed \$11.5 million, and of the \$11.5 million we questioned \$3.6 million. So then we took the \$3.6 million away from the initial total amount that they submitted and reduced that to \$22.6 million. Based on the portion of the total indirect costs that is supposed to be paid by the Department of Labor, the OIG audits recommended Labor's share be reduced by \$622,575.

Senator HARKIN. So the \$3.6 million questioned is represented on the left-hand chart?

Mr. MASTEN. That is correct. And one of the things that was questioned on the first chart, if you notice the Tokyo office—\$510,000, because of the OIG audit, the initial \$26.2 million was reduced. The saving to the Department of Labor as it relates to the Tokyo office was \$100,000—just in that one particular expense alone.

While the Department, as I said earlier, no longer uses this contractor, it may take several more years for the indirect cost negotiation, audit resolution, and administrative appeal processes to be exhausted. Until then, in effect this contractor has an interest and penalty-free cash advance from the Government. Included in my full statement are three other examples that further illustrate the types of abuses my office has identified.

Mr. Chairman, I believe that inclusion of improper charges to grants and contracts persists because there is no strong incentive for grantees and contractors to stop including unallowable indirect costs such as those listed on the first table. In fact, there is a strong financial incentive to include them. After all, Mr. Chairman, contractors and grantees know in most cases they will simply have to pay the money back in depreciated dollars after having free use of advanced funds for many years.

Mr. Chairman, as stated earlier, the Department of Defense is authorized to charge interest back to the date of expenditure on disallowed costs paid by the Government. It is also authorized to charge penalties equal to the disallowed costs plus interest on the costs actually paid by the Government. It can also charge penalties three times the amount of the disallowed costs for indirect cost proposals containing costs that were previously determined to have been unallowed and/or in the amount of \$10,000 for each proposal submitted to the Government. Penalties can be assessed even if the improper charges were not actually paid by the Government.

Unfortunately, civilian agencies like the Department of Labor do not have such authority. For civilian agencies, interest does not come into play until after a final management decision is made and the Agency issues a debt collection notice.

AUDIT REPORTS

At DOL, this is exacerbated because under the Job Training Partnership Act Program, the program under which most of our audits fall, all Agency appeals must be exhausted before DOL can seek to collect any misspent funds and, therefore, any interest and penalties. This is often many years after the contractor or grantee has improperly used the Government's money. Therefore, in a nutshell, since the Government funds are interest and penalty free it is worth big dollars to the contractor and grantees to exhaust the appeal process and delay as long as possible repaying the advanced funds.

For example, Mr. Chairman, back in 1982 and 1983, the OIG issued four audit reports on a CETA grantee concluding that the grantee had charged improper administrative costs on its CETA grants between 1977 and 1980. Since the audit reports were issued, the questioned costs have been under continuous appeal. In 1990, the ALJ ordered repayment of \$3.4 million. The grantee appealed that ALJ's decision and since 1990, the case has been pending review and final decision in the Secretary's Office of Administrative Appeals.

Mr. Chairman, I draw your attention to table No. 2 to my right here, the last one on my right. As you can see, even if the Secretary issued a final decision today, May 13, 1994, this grantee would have to pay no interest up until today on the millions of dollars it improperly collected from the Federal Government 14 to 17 years ago.

If the Government was authorized to assess penalties and interest from the date of the improper expenditure or the date when the costs were reimbursed, the OIG calculates that for the \$3.4 million disallowed, the grantee would owe almost \$10 million in interest alone. That is the first amount on the chart here, as an example, to address the question earlier asked, why do they do it? From the business sense, why not? \$3.4 million interest free for that period of time.

Mr. Chairman, the Government cannot audit every dollar awarded; therefore, a deterrent needs to be built into the system to eliminate the financial incentive that currently exists to include improper charges and claims to the Government. Civilian agencies need authority to: (1) deter contractors from routinely including unallowable, unallocable, and all unreasonable costs in their claims to the Government; and (2) compensate the Government for the grantee's or contractor's use of any funds paid in excess of the amount to which it is entitled.

Therefore, the OIG supports legislation to authorize civilian agencies to assess interest, back to the date of expenditure or reimbursement, and assess penalties for including improper charges and claims to Government grants and contracts. This proposed penalty and interest authority for civilian agencies should be consistent with what is presently available to DOD.

It is my understanding that the Senate is now considering legislation introduced by Senator John Glenn which relates to Government procurement and includes a provision similar to what we are proposing.

Mr. Chairman, I would like to emphasize that it is important that the Government maintain an effective appeals system that properly ensures due process for grantees and contractors. However, just as the Internal Revenue Service is authorized to assess interest and penalties against taxpayers that fail to comply with the law, it seems only appropriate and equitable that other agencies should be similarly authorized to assess interest and penalties against grantees and contractors that attempt to have the taxpayers pay for their unallowable costs.

In fact, it is important to note that taxpayers have to pay Internal Revenue Service up front, and then they are allowed to appeal. Our proposal is simply that after all appeals have been exhausted, contractors and grantees should have to pay what they owe plus any retroactive interest and/or penalties dated back to the time the costs were incurred or paid by the Government.

FECA FRAUD

Mr. Chairman, before concluding the summary of my written statement I would like to thank you for the language you inserted in DOL's 1994 appropriations bill prohibiting the use of appropriated funds to pay Federal Employee Compensation Act benefits to those individuals convicted of FECA fraud. As a result of your legislative action, in just five OIG cases alone, the Office of Workman's Compensation Programs has recognized a potential lifetime savings of over \$4 million. At your request, in my full statement I have outlined what I consider to be permanent remedies to this problem.

PREPARED STATEMENT

Mr. Chairman, that concludes my oral statement. Mr. Peterson and I will be pleased to answer any questions you or the committee members may have at this time.

[The statement follows:]

STATEMENT OF CHARLES C. MASTEN

Good morning Chairman Harkin and subcommittee members, thank you for inviting me to testify before you in my capacity as the Inspector General of the U.S. Department of Labor on the issue of indirect cost abuses by grantees and contractors. From the onset, I would like to emphasize the views expressed today are mine as Inspector General and may not be the official position of the U.S. Department of Labor.

BACKGROUND

By way of background, the Federal Acquisition Regulation [FAR] sets forth cost principles for Government contracts. Similar requirements for grants are found in various OMB Circulars. The FAR and the OMB Circulars specify that contractors and grantees may only claim costs—both direct costs and indirect (overhead) costs—that are allowable, allocable to the contract or grant activity, and reasonable and necessary in the conduct of the contract or grant.

When Federal agencies award grants and contracts, the Government agrees to be responsible for that portion of the grantees' or contractors' total indirect costs that are used to administer the specific grant or contract. If the grantee or contractor

submits unallowable expenses as part of its indirect costs, it can result in the Government paying a higher share of the indirect costs than it should.

The Office of Inspector General is responsible for auditing costs claimed by grantees and contractors and for making recommendations that the Department disallow costs determined by the audit to be improper. Many of these audits are conducted at the request of the Department.

Once OIG audits a grantees' or contractors' proposed final indirect cost submission and we question certain costs as improper charges, the OIG provides the Department with an audit-recommended final indirect cost rate. The final indirect cost rate ultimately determines how much is owed to the Department or to the grantee. The OIG-recommended indirect cost rate is then considered by the Department's Office of Cost Determination in negotiating a final indirect cost rate with the grantee or contractor. However, if agreement is not reached, that office will make the unilateral determination on the final indirect cost rate, which is then subject to appeal.

Mr. Chairman, the OIG can audit only a very small percentage of the entire universe of DOL grants and contracts. However, OIG audit findings, coupled with findings by GAO and other Government agencies, lead me to believe that improper charges to grants and contracts (particularly indirect costs) are a growing, widespread problem that potentially affects not just the Department of Labor, but all Government agencies as well.

OIG AUDIT FINDINGS

Despite the requirements under the FAR and the OMB Circulars, my office continues to identify substantial unallowable costs in our audits of contractor and grantee indirect costs. For example, my office just issued three audit reports questioning over \$3.6 million of the total incurred indirect costs claimed by a Job Corps support contractor. For the 3-year period, this contractor claimed \$26.2 million in total incurred indirect costs, with \$7.75 million allocated to DOL. DOL's share of the questioned indirect costs is \$622,575. Needless to say, the contractor disagrees with almost all of OIG's questioned costs.

Mr. Chairman, listed in Table 1 are some of the costs that were questioned for this contractor because the costs were personal in nature in that they were incurred by the company president or on his behalf. Included were such items as:

- \$1.03 million for personal travel expenses (first-class and chartered air travel, inadequately documented travel, limousine rentals, exorbitantly priced hotel rooms, etc.);
- \$683,000 for personal residence expenditures (depreciation on household furnishings, building and grounds maintenance, rent, utilities, etc.);
- \$510,000 for an office in Tokyo that provided no service or benefit to the DOL contract;
- \$275,500 for entertainment;
- \$257,000 for non-business professional services (advertising and public relations);
- \$203,000 for freight, customs and storage of personal household items;
- \$71,000 for social or civic club memberships;
- \$70,000 for liquor; and
- \$55,000 for dry cleaning.

Table 1.—Types of costs included in total indirect cost claims

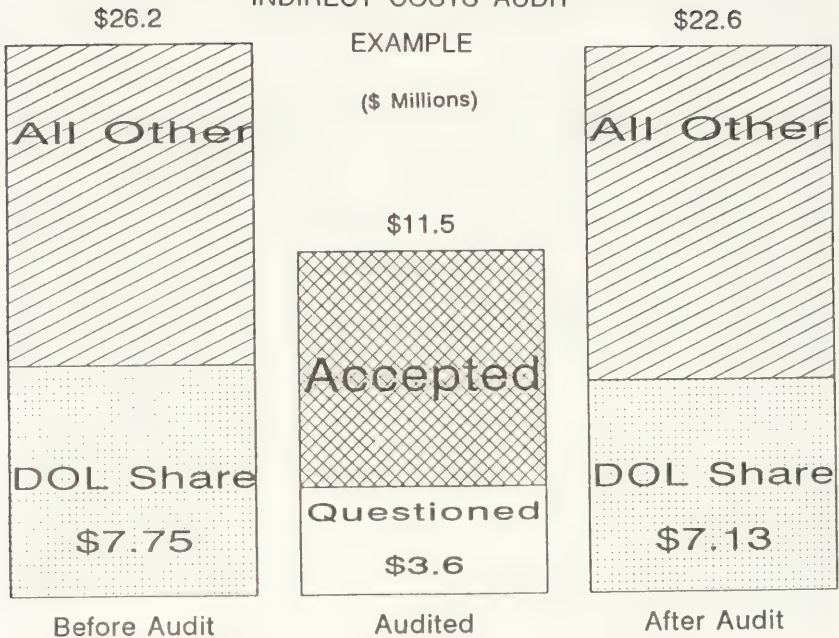
[Department of Labor would pay a portion]

Personal expenses: First class/chartered air travel, limousine rentals, expensive hotel rooms	\$1,030,000
Personal residence expenditures: Depreciation on household furnishings, building and grounds maintenance, rent, utilities	683,000
Tokyo office: Provided no benefit to the Department of Labor contract	510,000
Entertainment	275,000
New-business advertising and public relations	257,000
Freight, customs, and storage of personal items	203,000
Social/civic club memberships	71,000
Liquor	70,000
Dry cleaning	55,000

The bar graph (Chart 1), illustrates how the Government can ultimately pay for a portion of these costs.

CHART 1

INDIRECT COSTS AUDIT



$\$7.75 \text{ million} - \$7.13 \text{ million} = \$622,575$
 OIG Recommended Reduction in DOL Share

Mr. Chairman, the OIG reviewed \$11.5 million of the company's total incurred indirect costs which, as I stated, totalled \$26.2 million over a 3-year period. The audit questioned roughly one-third of the \$11.5 million reviewed—that is \$3.6 million.

Therefore, the total incurred indirect costs claimed (\$26.2 million) was reduced by the \$3.6 million questioned. This new audit-recommended total incurred indirect costs (\$22.6 million), if accepted by the Department's Office of Cost Determination, will subsequently reduce DOL's share by \$622,575. Had these costs not been detected and challenged as unallowable, the Government would have been responsible for a portion of those unallowable costs. For example, in the case of the Tokyo Office, the Government would have been responsible for almost \$100,000.

While the Department no longer uses this contractor, it may take several more years for the indirect cost negotiation, audit resolution, and administrative appeals processes to be exhausted. Adding insult to injury is the fact that the company also overdraw its interim payments from DOL by \$219,440. Therefore, as a result of the \$622,575 of the DOL share recommended by the OIG to be disallowed (and which was previously advanced) and the \$219,440 overdrawn from DOL by the contractor, in effect, this contractor has an interest and penalty-free advance from the Government in the amount of \$842,015.

Another example of the types of problems in this area involves a major non-profit organization, which is a national sponsor under the Senior Community Service Employment Program. The grant provides employment and training opportunities to low-income individuals age 55 and over. In 2 audits issued on this grantee for a 3-year period, the OIG questioned \$1.4 million in costs, with a DOL impact of \$1.2 million. Most of the questioned costs resulted from improper salaries and fringe benefits charged to the overhead account and excessive allocation of non-personnel costs. This grantee improperly charged the time of employees who worked on non-Federal programs and its own fundraising and membership activities to the total overhead costs account. By improperly charging the time as indirect costs, the grantee shifted to DOL substantial costs assignable to non-DOL activities.

The Department has disallowed \$805,246 of the \$1.2 million allocated to DOL for the 3 years. Therefore, this grantee may now owe the Department as much as \$805,246, for funds received more than 4 years ago. Again, as in the previous case, until all administrative appeals have been exhausted, the grantee has an interest-free and penalty-free advance from the Federal Government.

Mr. Chairman, my office also found serious problems in three audits of a Job Corps support contractor that provided real estate management support services for over 100 Job Corps Centers nationwide. The audits reviewed expenditures for 1986-90.

The questioned costs resulted from transactions which, when taken collectively, indicated a pattern of program abuse. This contractor claimed unallowable costs, including numerous personal expenses (i.e., one semester of college tuition for the company president's son, family vacations, clothing, jewelry, food items, and cable television service to their personal residence), that directly benefitted the president and his family. This contractor also charged the DOL contract for unallowable wages and fringe benefits paid to family members which were (a) in excess of contractual ceilings or (b) incurred for non-Job Corps activities.

As a result of the OIG's audit findings, the Department has disallowed costs totaling \$365,323 and has terminated its relationship with this contractor. The Department has mailed the contractor Debt Collection Notices; however, all mail from DOL has been refused. The Department is preparing the case for referral to the Department of Justice for debt collection action. However, no interest can be assessed for the 4 to 8 years the contractor had use of the Government funds prior to the Department issuing the Debt Collection Notices.

Finally, we have the case of a national, non-profit organization that receives grants from the Department for job training programs for youth. After auditing their grants for the period of 1987-89, the OIG questioned almost \$800,000. The questioned costs resulted primarily from the grantee improperly claiming a disproportionate amount of general and administrative costs under its grants. This grantee used predetermined, rather than actual, percentages and amounts to allocate its administrative costs and included unallowable costs in the general and administrative cost pool. In addition, the grantee failed to reduce the overall rental expense for rental income received for sublet space.

Following an administrative hearing on the costs disallowed by the Employment and Training Administration, the Administrative Law Judge ordered the grantee to pay \$622,602. The contractor then appealed to the Secretary. This past February, the Secretary refused to accept the case for review. With all administrative appeals exhausted, the grantee is now seeking judicial review in the United States Court of Appeals.

Although interest started to accrue in February as a result of the Secretary's final decision, this contractor had free use of \$622,602 in Government funds for some 7 years.

FINDINGS BY OTHER GOVERNMENT AGENCIES

Mr. Chairman, these are just a few examples of the abuses that my office has documented through our audits of contractors and grantees. Reviews by GAO, HHS, and other Federal agencies have yielded similar results and conclusions. In fact this past March, GAO testified before the Senate Budget Committee that:

"Over the years, our office has issued numerous reports on contractor overhead costs * * *. Our work and the audits of the Defense Contract Audit Agency and the Inspectors General show that unallowable and questionable overhead costs are a significant and widespread problem—costing Federal agencies and American taxpayers potentially hundreds of millions of dollars annually."

OMB "SWAT TEAM" TASK FORCE

The audit findings have been of such significance that, in 1992, OMB convened a Government-wide task force, known as the SWAT Team Task Force, to study contract administration practices in 12 major civilian agencies. My office took a very active role in the task force which found recurring instances of contractors seeking reimbursement for "questionable costs, such as alcohol, gold watches, parties, tickets to sporting events, and social club memberships." The individual agency SWAT team reviews confirmed the Inspectors General's findings and found serious weaknesses which could permit the payment of unallowable costs.

The task force literally made hundreds of recommendations for improving the administration and management of government contracts. Among the recommendations was the need for enactment of legislation that would provide for civil penalties and interest on unallowable costs submitted to civilian agencies.

GRANTEES AND CONTRACTORS CAN EXPLOIT THE SYSTEM

Mr. Chairman, I believe that inclusion of improper charges to grants and contracts persists because there is no strong incentive for contractors to stop including unallowable indirect costs (such as those mentioned earlier) in their claims to the Government. In fact, there is a strong financial incentive to include them. After all, Mr. Chairman, contractors and grantees know, in most cases, they will simply have to pay the money back in depreciated dollars after having the free use of the advanced funds for many years.

Mr. Chairman, unlike the Department of Defense which is authorized to charge interest and penalties back to the date of expenditure, civilian agencies like the Department of Labor do not have such authority. The Department of Defense is authorized to:

(1) Charge interest—back to the date of expenditure on the disallowed costs paid by the Government; and

(2) Charge penalties:

—Equal to the disallowed costs (plus interest on the costs actually paid by the Government),

—Three times the amount of the disallowed costs, for indirect cost proposals containing unallowable costs that were previously determined to have been unallowable, and/or

—In the amount of \$10,000, in addition to other interest and penalties, for each proposal submitted to the Government.

Penalties may be assessed even if the improper charges were not actually paid by the Government.

Unfortunately, civilian agencies like the Department of Labor do not have such authority. For civilian agencies, interest does not come into play until after a final management decision is made and the Agency issues a debt collection notice. At DOL this is exacerbated because, under the Job Training Partnership Act (the program under which most of our audits fall), all agency appeals must be exhausted before DOL can seek to collect misspent funds and, therefore, any interest and penalties. This is often many years after the contractor or grantee has improperly used the Government's money.

Therefore, in a nutshell, since these funds are interest-free and penalty-free, it is worth big dollars for the contractors and grantees to exhaust the appeal process, for as long as possible, in order to delay repaying the advanced funds.

For example, Mr. Chairman, back in 1982 and 1983, the OIG issued four audit reports on a CETA grantee concluding that the grantee had charged almost \$9 million in improper administrative costs on its CETA grants between 1977 and 1980. Ever since the OIG audit reports were issued, the questioned costs have been under continuous appeal. In 1990, the ALJ ordered repayment of \$3.4 million.¹ The ALJ decision was appealed and, since 1990, the case has been pending review and final decision in the Secretary's Office of Administrative Appeals.

Mr. Chairman, I draw your attention to Table 2. As you can see, even if the Secretary issued a final decision today, May 13, 1994, this grantee would have to pay no interest up to today on the millions of dollars it improperly collected from the Federal Government 14 to 17 years ago. If the Government was authorized to assess interest and penalties from the date of the improper expenditure (or the date when the costs were reimbursed) the OIG calculates that, for the \$3.4 million disallowed, the grantee would owe almost \$10 million in interest alone.

TABLE 2.—IF THEY HAD TO PAY TODAY

Grantee/contractor	Amount	Interest under current law	Interest under proposed law
CETA grantee (1977-80)	\$3,391,483		¹ \$10,000,000
SCSEP national sponsor (1988-90)	805,246		¹ 275,000
Job Corps support contractor (1988-90)	622,575		¹ 200,000

¹ Over.

Mr. Chairman, in addition to the financial incentives to inflate the indirect costs claimed, contractors and grantees know that their chances of getting caught are minimal. This is because their cost submissions are often finalized without on-site review by either cost negotiators or auditors because of limited Federal oversight

¹ This figure is comprised of 2.6 million disallowed on the four audits issued in 1982 and 1983 as well as \$800,000 from six other audits.

resources. Even if caught, they have little to fear since defunding, debarment action, or prosecution is seldom pursued.

LEGISLATIVE RECOMMENDATIONS

Mr. Chairman, the Government cannot audit every dollar awarded. Therefore, a deterrent needs to be built into the system to eliminate the financial incentive that currently exists to include improper charges in claims to the Government.

The OIG is of the opinion that civilian agencies need such authorities to: (1) deter contractors from routinely including unallowable, unallocable and/or unreasonable costs in their claims to the Government, and (2) compensate the Government for the grantee's or contractor's use of any funds paid in excess of the amount to which it is entitled. Therefore, the OIG supports legislation to authorize civilian agencies to:

- Assess civil penalties for including unallowable, unallocable and unreasonable costs in claims to Government grants and contracts, and
- Assess interest charges from the time the Government reimburses the grantee or contractor for the improper charge (or the expenditure is made with advanced funds) until the time that repayment is made.

The proposed penalty and interest authority for civilian agencies should be consistent with what is presently available to DOD.

It is my understanding that the Senate is now considering legislation proposed by Senator John Glenn that relates to Government procurement and includes a provision similar to what the OIG is proposing.

Before concluding on this issue, Mr. Chairman, I would like to emphasize that the OIG believes it is important to maintain an effective appeal system that ensures due process for grantees and contractors. However, just as the Internal Revenue Service is authorized to assess interest and penalties against taxpayers who fail to comply with the law, it seems only appropriate and equitable that other agencies should be similarly authorized to assess interest and penalties against grantees and contractors that attempt to have the taxpayers pay for their unallowable costs.

In fact, it is important to note that taxpayers have to pay the IRS up front—and then they can appeal. Our proposal simply states that once all appeals have been exhausted, contractors and grantees should have to pay what they owe, plus any retroactive interest and/or penalties dating back to the time costs were incurred or paid by the Government.

FRAUD IN THE FEDERAL EMPLOYEES' COMPENSATION PROGRAM

Mr. Chairman, in your letter of invitation you also requested that I discuss the effect of the provision included in the Department's fiscal year 1994 Appropriations Bill prohibiting the payment of benefits to persons convicted of defrauding the Federal Employees' Compensation Act [FECA] Program and additional legislative remedies needed to further prevent fraud and abuse of this program.

First, thanks to language you inserted in DOL's 1994 Appropriation Bill, effective October 21, 1993 and through fiscal year 1994, DOL is no longer required to pay benefits to those convicted of FECA fraud. Under Section 102, Congress prohibited the use of any appropriated funds to pay any benefits, compensation, or other related expenses to individuals convicted of a violation of § 1920 of Title 18 of the U.S. Code, or any felony related to the application for, or receipt of, FECA benefits.

I am pleased to report that, working with OIG investigative results, the Office of Workers' Compensation Programs [OWCP] has been quick to utilize the language contained in the fiscal year 1994 DOL Appropriations Bill to terminate the FECA benefits of individuals who have been convicted of FECA fraud.

For example, in just five OIG cases, OWCP has recognized an immediate annual cost savings to the Government of \$120,263. Using the life expectancy of the individuals involved (based on current mortality rates), the potential lifetime loss to the Government in these five cases could have exceeded \$4 million in taxpayer money had benefits not been quickly terminated as your legislative action enabled us to do. These figures certainly help to illustrate the financial impact of enacting permanent legislation that would amend the Federal Employees' Compensation Act and § 1920 of Title 18 of the U.S. Code.

Unfortunately, OWCP could not automatically terminate the benefits of all who have been convicted of FECA fraud and continue to receive FECA benefits because provisions under the fiscal year 1994 DOL Appropriations Bill are not retroactive. For example, benefits collected by a former Defense Construction Supply Center employee who had previously pled guilty to two counts of theft of public funds could not be terminated because the conviction took place prior to October 21, 1993. It is very disturbing for me to have to report to you, Mr. Chairman, that as we speak, this former employee is confined to a Federal prison where she is serving time for

FECA fraud while continuing to receive FECA benefits of over \$838 every 28 days. Moreover, she stands to receive some \$33,545 in tax-free FECA benefits—over the period of her jail sentence—all from the program she was convicted of defrauding.

Mr. Chairman, as you are aware, the OIG, in conjunction with OWCP, has long recommended enactment of legislation that would permanently amend the Federal Employees' Compensation Act as well as the appropriate sections of Titles 5 and 18 of the U.S. Code to: (1) Terminate benefits to claimants convicted of FECA fraud, (2) Suspend payment of benefits to individuals incarcerated for any felony offense during the period of time they are in prison, with any dependents receiving reduced benefits (similar to social security benefits under the social security system), and (3) Raise the level of a violation of § 1920 of Title 18 of the U.S. Code from a misdemeanor to a felony.

The OIG vigorously supports permanent legislative changes to fully address these three OIG recommendations and looks forward to continuing to work with your Subcommittee to this end.

Mr. Chairman, this concludes my prepared statement. I would be pleased to answer any questions you or the other Subcommittee Members may have.

Mr. Chairman and members of the subcommittee, I appreciate this opportunity to appear before you to discuss the fiscal year 1995 budget request for the Office of Inspector General [OIG], Department of Labor [DOL].

The OIG's fiscal year 1995 budget request totals \$53,001,000 and 490 full-time equivalent positions. This request is a net increase of \$1,501,000 and a decrease of 10 FTE below the fiscal year 1994 allowance level. The principal elements for the net increase are:

- \$1,700,000 to allow for built-in and mandatory increases to cover costs associated with personnel compensation and benefits;
- \$899,000 to allow for a 2.9 percent increase for built-in and mandatory increases to cover costs associated with non-personnel compensation;
- \$500,000 related to the enforcement initiative for ADP increase;
- \$138,000 decrease for one less day of pay;
- \$376,000 decrease for a 3 percent administrative reduction to comply with Executive Order 12837; and
- \$1,084,000 decrease for eliminating 10 FTE which was identified as part of the 100,000 position reduction to streamline Government required by Executive Order 12839.

The OIG's total budget is distributed among five program areas: the Office of Audit, the Office of Investigations, the Office of Labor Racketeering, the Office of Resource Management and Legislative Assessment, and Program Direction.

OFFICE OF AUDIT

The request for the Office of Audit totals \$23,767,000 and 217 FTE, \$246,000 above and 5 FTE below the fiscal year 1994 estimate.

In fiscal year 1995, the Office of Audit will continue to carefully plan work to prioritize those areas for audit that have large dollar expenditures or are more vulnerable to fraud, waste, and abuse.

The Office of Audit will still have as its main priority both the specific requirements assigned by the Chief Financial Officers Act of 1990, and the additional related requirements mandated by OMB. These are detailed on page OIG-13 of our budget justification package. Beyond that effort, the Office of Audit will maintain the broadest possible audit coverage of Departmental program operations and management. Substantial fiscal year 1995 audit coverage will be dedicated to the areas of: Contract and Grant Management and Administration; Training Programs; Enforcement of ERISA Protection for Pension Plan Participants; Unemployment Insurance Quality Control and Program Statistics; and Implementation of JTPA Legislative and Regulatory Changes.

The amount requested for the Office of Audit includes \$4,174,000 in audit contracting funds, which is the equivalent of 52 FTE. Coupled with the Office of Audit's 217 FTE, Audit anticipates performing 147 audits, studies, and reviews; and issuing 325 audit reports under the Single Audit Act.

OFFICE OF INVESTIGATIONS

The request for the Office of Investigations totals \$9,051,000 and 99 FTE, \$106,000 above and 2 FTE below the fiscal year 1994 estimate.

The Office of Investigations program priorities will be in the areas of the Job Training Partnership Act, the Federal Employees' Compensation Act, interstate un-

employment insurance fraud, and DOL employee misconduct. Additionally, the Office of Investigations will proceed with its oversight responsibilities to detect vulnerabilities in DOL programs and operations. The Office of Investigations plans to devote more time to FECA fraud schemes including medical providers who are a part of these schemes.

Due to the 2 FTE decrease in fiscal year 1995, the Office of Investigations caseload projections for 1995 are below those of fiscal year 1994.

OFFICE OF LABOR RACKETEERING

The request for the Office of Labor Racketeering totals \$12,600,000 and 115 FTE, \$710,000 above and 2 FTE below the fiscal year 1994 estimate.

The Office of Labor Racketeering's enforcement program is founded on the premise that organized criminal groups have penetrated certain labor organizations and used unions as vehicles to abuse affiliated employee benefit plans and create criminal monopolies in labor intensive industries. These industries include the building and construction, waterfront, garment, trucking, waste disposal, and tourism trades.

A unique feature of this enforcement effort is its commitment to long-term investigative projects designed to reach beyond the most visible violations and perpetrators in order to remove insulated persons who represent the infrastructure of corruption. Such a concentrated focus also is intended to promote a continuous law enforcement presence in historically corrupt areas in an effort to create a credible deterrent.

The Office of Labor Racketeering will continue, as in the past fiscal years, to conduct criminal investigations in the following priority areas: employee benefit plans, labor-management relations, and internal union affairs. Within the benefit plan arena, the primary focus will be upon welfare plans, including the burgeoning problem of fraudulent self-funded group health plans and fraudulent multiple employer welfare arrangements.

OFFICE OF RESOURCE MANAGEMENT AND LEGISLATIVE ASSESSMENT

The request for the Office of Resource Management and Legislative Assessment totals \$5,954,000 and 42 FTE, \$390,000 above and 1 FTE below the fiscal year 1994 estimate.

The Office of Resource Management and Legislative Assessment provides for legislative and regulatory assessment, personnel, payroll, procurement, automated data processing, and financial management support functions necessary to carry out the nationwide responsibilities of the Office of Inspector General on a timely and cost-effective basis.

PROGRAM DIRECTION

The request for the Program Direction function totals \$1,629,000 and 17 FTE, \$49,000 above the fiscal year 1994 estimate.

The Program Direction function provides for overall management and direction as well as policy development, planning and review, legal counsel, and internal review functions necessary to carry out the nationwide responsibilities of the Office of the Inspector General.

In addition, this functional area includes the Special Projects Office. This office will provide the Office of Inspector General with fast, objective and reliable data regarding narrowly focused issues concerning Labor programs and operations as well as internal operations and concerns of the Office of the Inspector General.

Mr. Chairman, this concludes my prepared statement. I again would like to express my appreciation for the opportunity to testify before you this day. My staff and I would be pleased to answer any questions you or your colleagues may have.

UNALLOWABLE OVERHEAD COSTS

Senator HARKIN. Mr. Masten, thank you very much for that testimony. You have given us numerous examples of unallowable overhead costs that Labor Department grantees and contractors have tried to get paid for, ranging from liquor to jewelry. Do you have any more details or specifics? Here are some of the examples that we identified that have come in, that we just know about, ranging from entertainment to jewelry, scuba diving, stereos, restaurants

and meals. I mean, you can see all them. Watch repair, I do not know what that was all about. We had college tuition paid for for the son, I think it was, of the president of the company.

OVERHEAD COSTS

Mr. MASTEN. Mr. Chairman, if I could give you an example. One of the meals, for example, was catered to a group of about 24 to discuss the plans for putting a building in a foreign country. That meal alone cost \$7,062.

Senator HARKIN. How many people?

Mr. MASTEN. I believe 24.

Senator HARKIN. How? What city was this in?

Mr. MASTEN. I do not recall the city, but the building was located, I believe, in Hong Kong.

Senator HARKIN. My goodness. How much is that? That is about \$250 a person.

Senator REID. More than that, is it not?

Senator HARKIN. How do you explain scuba diving and stuff like that?

Mr. MASTEN. I cannot, not as an indirect cost.

Senator HARKIN. How about the antique silver coin from a sunken Spanish galleon, what is that all about? Do you know what that is?

Mr. MASTEN. That is another one I cannot put my fingers on, Mr. Chairman, but I can assure you every item you have listed was identified through the audit process and was submitted by a contractor as an indirect cost.

Senator REID. This is only one contractor.

Mr. MASTEN. This is one contractor.

Senator REID. I thought this was a kind of a compilation of all of them.

Mr. MASTEN. No, no; that is one contractor. I thought I would use the most egregious examples to highlight here now, but there are three others. I am sorry, I stand corrected, it is a compilation of several audits. It is my understanding, for example, that the son's college tuition came from another vendor. But these are the types of examples of the indirect costs that I have mentioned in my total written testimony.

Senator HARKIN. In the past, in the previous years we have looked at some of these things, as the staff delved into this, we heard from some of the different grantees that the rules and regulations were not clear. And so they push it off on the fact that they really did not know what was allowable and was not allowable. Do you think that most contractors are ignorant of the law or are they really purposely trying to pad their expenses? Which is it?

Mr. MASTEN. Mr. Chairman, I do not think that all contractors purposely try to pad their expenses. But I can tell you, based on our audits, a lot of them do. And I think as I stated earlier, they do it because—why not? They are not going to have to pay the interest, they are not going to have to pay any penalties so why not stretch out having free use of the money?

Senator HARKIN. But that is purposely. I mean any contractor has got to know that scuba diving would not be something that the

Government would want to pay for. There are some of these things that are beyond the pale of even being reasonable.

Senator REID. Mr. Chairman, if I could interrupt, though, if you really follow what Mr. Masten has said—take college tuition as an example. I mean it is a way to borrow the money. You might have to pay it back, but by then maybe the kid will be out of school and he can pay it back himself. [Laughter.]

Mr. MASTEN. And he will pay it back interest free.

Senator HARKIN. What I mean by purposeful, this is with knowledge aforethought that they are doing this. I mean, they know what they are putting down. This is not some mistake in book-keeping.

Mr. MASTEN. I am of the opinion that individuals who can get these contracts have a good idea of what they are doing.

Senator HARKIN. I would think so.

Senator REID. Mr. Chairman, if I could just also—and then I will be quiet. There are a number of specific recommendations you have given in your written testimony, and I think we should closely follow those. And if the authorizing committees do not do something about them this year, I think you, again, should consider putting them on your appropriation bill. Because they are very specific. I mean, there is no beating around the bush. He is very specific about what he feels should be done, and I think we should follow those recommendations.

Senator HARKIN. We have been in contact with Senator Glenn. They are trying to get a bill through. Again, I am hopeful that Government Ops will do this. That is basically in their purview Governmentwide. But I am with you, Senator Reid. I think that if action is not taken there, we ought to take action on our own, at least under those things that are under our jurisdiction.

Senator REID. Yes; this is just terrible.

Senator HARKIN. Yes; we should not let it go another year. It is like you said, like the Department of Defense. They have to pay everything back with interest from the date that they got the money, right?

Mr. MASTEN. That is correct.

Senator HARKIN. But here you do not. I like the idea about IRS. That is true. In IRS they have to pay and then you appeal.

Mr. MASTEN. Exactly.

Senator HARKIN. That could even be a bigger deterrent. We might want to consider that, Senator Reid. I do not know. We might want to consider that in terms of unallowable costs like this.

Mr. MASTEN. Exactly. I would accept either one.

Senator HARKIN. Oh, I know what I wanted to ask you. You talked about the strong financial incentive. You know, you do not have to pay it back, it is interest free, there is no penalty, right?

Mr. MASTEN. Right.

Senator HARKIN. There is no fine, such as a \$10,000 fine, no 5 years in jail, nothing like that, right?

Mr. MASTEN. That is correct.

FALSE CLAIMS ACT

Senator HARKIN. Is there no way currently to prosecute these contractors under the False Claims Act or any other authority of the Federal Government?

Mr. MASTEN. In cases where fraud can be proven, the False Claims Act or in the cases involving less than \$150,000, the Program Fraud Civil Remedies Act, are remedies that the Government can use. The problem, though, with using these two acts is that it is very hard to prove the fraudulent intent. As we speculated earlier, you know, do they know it, that is one thing. But to prove the fraudulent intent that is necessary to prosecute the cases either administratively, civilly, or criminally, is very very difficult.

And without considerable additional investigative effort in addition to the audit work that is already done, it is very very costly, it is extremely hard to show that the statements or the claims submitted by the contractors were false. There is also a difference, Mr. Chairman, between the false and fraudulent claims and the claims which are improper and unallowable. We believe that the authority to impose interest and penalties back to the date of expenditure or reimbursement would serve as a good middle ground to deter these individuals from doing this.

I am trying to draw a distinction between the fraudulent and the improper submission of these costs, with the rules, as they are now, they submit the improper indirect costs risking that they are not going to be audited, that they are not going to be caught, so, why not do it? And I think that is what has happened in a lot of cases. And if you do it and you stretch it out for a long period of time, since you do not pay any interest or penalty, why not take a chance?

APPEALS PROCESS

Senator HARKIN. Yes; I guess to prove fraud you would have to go through a long court process, appeals process. I guess the other question I have is a contractor like this that you pointed out over here, is there any debarment procedure? In other words, once they get caught submitting these kinds of claims that are unallowable, are they put on any kind of list and debarred from submitting bids to the Government in the future for grants?

Mr. MASTEN. Mr. Chairman, when we come upon these types of egregious circumstances, we go back to the Department with our audit finding it in turn, will often stop using the contractor, as it has done in this case. But debarment of these grantees or contractors is very seldom used. When we recommend that DOL stop using them or recommend that DOL cut the funds, the Department usually responds.

Senator HARKIN. Why is it so seldom used? Is that a Department regulation? I mean that is something that is out of your purview, right?

Mr. MASTEN. Right. I will refer that to Mr. Peterson.

Mr. PETERSON. I think one of the reasons it is so seldom used is the Department has made a decision not to seek debarment until all administrative remedies are sought. And so it is a long time after the fact. I think most of these are defunded. That is to say,

the Department did act quickly to cut this contract off and by the time the administrative procedures are all satisfied the Department has lost its interest in debarring that contractor. So I think it is more of a timing problem. I think the Department does act swiftly in cutting off the contract, but a debarment action for these grantees or contractors is very, very seldom taken.

Senator HARKIN. But it seems to me, like in that CETA contract you were talking about, you were talking about 14 to 17 years there. I mean, that contractor could have had a lot of other contracts rolling on through the years, making a lot of money, and I do not know if they have been audited on some of their other grants, but it would seem to me that maybe if these unallowable costs are caught by an audit and verified, that, again, there should be some type of immediate debarment.

That, then, would, I think, prod that contractor to seek an early resolution of this case so that they might get further contracts. In other words, get over it, pay a penalty, pay the interest, something like that, get back in good standing. But if you do not, then their interests is in dragging it out for as long as possible.

Mr. MASTEN. That is correct, Mr. Chairman.

Senator HARKIN. I mean there is no constitutional right, is there, that I can understand that I know of, for a contractor to get a grant. I do not think there is a constitutional right.

Mr. MASTEN. No; I agree with you. As far as I know, there is no constitutional right for a contractor to get it.

DEBARMENT ACTION

Senator HARKIN. That is what we ought to look at, is debarring right away when we find that, and then put the burden on them.

Senator REID. To be reinstated.

Senator HARKIN. That is right. I think we ought to look at that too. Again, I do not see any constitutional problem there.

Senator Reid, I can yield to you if you have anything else. I do not know if I had any other things.

There is one area that in looking at some of the things we got from you earlier on, you discussed a number of instances where contractors or grantees charged improperly the time of employees to Federal contract grants. It almost looks like there is a double billing going on there, like some of the people were paid from someplace else but they put that request in for salaries and expenses again. And then charging excessive salary costs for someone that should only, under the contract, have been paid \$50,000, they are now being paid \$100,000.

Is there much of this going on and should there be strict limits on the salaries of contractual employees that can be charged to the Government?

Mr. MASTEN. Mr. Chairman, first let me draw a distinction between improper salary charges described in my full testimony and what you have mentioned as being excessive, or the double billing part. We have conducted many audits, including those identified in my testimony, that have identified instances in which contractors and grantees have allocated employee salary expenses to DOL when they were working on non-DOL activities. The problem with

this is that the contractor has improperly allocated the salary to that contract as it relates to DOL.

On the subject of excessive salaries, I bring to your attention an audit that we issued in 1990 which examined the compensation of a number of Job Corps Center operators. Our general conclusions were that the amount of compensation, particularly salaries and bonuses paid to some of the executives there and charged to the indirect costs pool for allocation to both DOL and non-DOL programs, could be considered unreasonable by virtue of the type of program involved, the Job Corps Program.

To say that there should be a limit, though, on the amount of a salary that is paid, there is no statutory requirement for that. However, I think that the salary should be part of the overall center operating cost, that is, on what it is going to cost to get whatever product you are purchasing. The salary will become a part of that cost. And if the result is going to be cost effective, then I think you should look at that before you issue the contract, not after the fact.

EXECUTIVE COMPENSATION

Senator HARKIN. Could you give us some details on how much salary we are talking about here and bonuses? What are we talking about here?

Mr. MASTEN. If you do not mind, Mr. Chairman, I will defer on that to Mr. Peterson.

Mr. PETERSON. In 1990 we looked at the salaries and bonuses of a number of the presidents of corporations that were operating Job Corps Centers, a percentage of which were charged to the Job Corps Program, as follows: \$72,738, \$184,208, \$93,916, \$125,000, two at \$138,000, and \$135,000. It ranged from a high of \$184,000 down to \$44,000. These were compensation packages for the presidents of those companies that were running Job Corps Centers for the Job Corps Program, sir.

We did not necessarily conclude whether or not that was too high or not, although we said you ought to look at it in terms of the nature of the program that you delivering. But we could not find any relationship between the amount of the executive's compensation and the number of Job Corps student slots for which they were responsible. We believe a range of \$61 to a high of \$868 in cost-per-student-slot of executive compensation is unreasonable, and that is the kind of variation we found.

What we suggested to management at that time was that they formulate some plan to look at this salary, not in terms of slots, but outcomes. And to their credit, Job Corps management has made this a review item in the reissuance of their contracts.

Senator HARKIN. Were those salaries actually charged to Job Corps?

Mr. PETERSON. Those were the portions charged to Job Corps.

Senator HARKIN. Were there any bonuses on top of the salaries?

Mr. PETERSON. That was salary and bonuses, sir. Actually, the figures I gave you was what was actually charged for and paid by Job Corps. The salaries were much larger than that, in total, but the piece I gave you was the Job Corps reimbursement.

Senator HARKIN. Well, one last thing that I have is you suggested that the Government be allowed to charge interest and penalties. Do you think it would make sense to allow those penalties collected to be used for further investigations of unallowable costs rather than being returned to the Treasury? Again, we are always facing a problem in our Appropriations committee of trying to find enough money for inspections and audits.

But we know that taxpayers make out if for every dollar that we spend on the inspector general's office in your case, we are getting back \$8 or more for the taxpayers of this country. And yet we are finding a real problem because of reductions in FTE's and everything else Governmentwide, that we are being forced to make some cutbacks here too. But I am wondering if, in fact, we are able to have some penalties and things like that, that maybe that money ought to stay in for further investigations to find other unallowable costs. I just wonder if you have any thoughts on that.

Mr. MASTEN. I am concerned that a proposal such as that, Mr. Chairman, drives the audit process more into compliance auditing and away from performance evaluations of billion-dollar programs. So while additional funds for audits and investigations are always welcome, we have not fully examined the ramifications of this type of proposal and I am not prepared to really address that at this time.

Senator REID. Mr. Chairman.

Senator HARKIN. Go right ahead, Senator Reid.

Senator REID. Before you leave, go over one of these with me again. Now, after you have made a determination that these are nonchargeable costs, do we have to get the money back from the contractor or are they asking us to pay this?

Mr. MASTEN. We have to get it back.

Senator REID. I will bet a lot of this, after all the time it takes, these businesses could be gone.

Mr. MASTEN. That is correct. Some of them are.

Senator REID. That is really a bad deal.

Senator HARKIN. That is. That is why we need to go after this.

Senator REID. See, that amplifies the point about using our money.

Mr. MASTEN. It sure does, sir.

Senator HARKIN. I am shocked that we cannot charge penalties and interest and we do not have a more rapid debarment procedure than what we have. Long overdue.

Unless you have anything else, Senator Reid, thank you very much, Mr. Masten, thank you Mr. Peterson, again.

Mr. MASTEN. Thank you for inviting me, sir.

Senator HARKIN. Thank you.

Senator REID. Mr. Chairman, this is one of those hearings I kind of wish I had not come to. We are better off not knowing some of this stuff.

DEPARTMENT OF EDUCATION

OFFICE OF INSPECTOR GENERAL

STATEMENT OF JAMES B. THOMAS, JR., INSPECTOR GENERAL

Senator HARKIN. Now we will hear from the Department of Education's inspector general, Mr. James Thomas.

Mr. Thomas, I reviewed your prepared statement, which contains a wealth of valuable information, as well as your concise summary statement. We will include your detailed testimony in the record in its entirety and ask that you proceed with your summary remarks. Welcome, and please proceed.

Mr. THOMAS. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, I am pleased to be here today to share with the subcommittee experiences of the Office of Inspector General concerning some of the most serious examples of abuse and fraud in the programs administered by the U.S. Department of Education. In line with the subcommittee's request, I will focus on the failure by many schools to pay required refunds on Federal student loans authorized under title IV of the Higher Education Act.

The major problem in the administration of the act's refund provision is that many schools fail to pay the refunds they owe to lenders. Students are being victimized by the schools' failure to pay loan refunds when the student withdraws from school during the period for which the loan was made. Students often are incapable or unwilling to pay for services they did not receive, and their loans go into default.

While the Federal Government, and ultimately the taxpayer, pick up the tab for the default claims by the guarantee agencies and for interest and special allowance payments to the lenders and secondary markets, the student borrower is held responsible for not only the entire amount of the loan, but for accrued interest and for collection costs that can be charged by the lender and the guarantee agency. The total amount owed by the defaulted borrower frequently accumulates to more than twice the original loan amount.

Permit me to use a fictional example to explain the problem. As is typically the case, Jane Doe is from an economically and educationally disadvantaged background and wants to better her life by returning to school. She decides to enroll in a vocational school and discovers that she would be able to do so with the help of a \$2,500 Federal loan. Because of personal problems, she decides to withdraw after attending classes for only 3 days and notifies the appropriate school officials.

According to the school's refund policy, the school is required to refund \$1,700 to Jane's lender. However, it fails to do so and Jane is notified by the lender that she must repay the full \$2,500, instead of the \$800 that is rightly hers to pay. After increasing har-

assessment by collectors, she eventually is told that, with capitalized interest and collection charges, she must pay about \$6,000 for the 3 days of instruction that she received.

While she still has the low-paying job she had when she enrolled in the vocational school, her financial situation is significantly worse because her wages are being garnished and income tax refunds due to her have been attached through the IRS offset procedures. She also learns that, because of her defaulted loan, she is ineligible for further Federal student aid she needs to pursue her educational goals and has been given a credit rating that will prevent her from obtaining a commercial loan for additional education or for any other purpose. She feels that her dreams for a better life have been destroyed by the very educational, financial, and governmental systems that have offered her deliverance.

Our investigators and auditors hear again and again of this kind of injustice perpetrated on student borrowers because of school failures to pay refunds. One such case involved a disabled veteran who, with the help of a Federal loan of about \$2,500, enrolled in a proprietary business school in Illinois. Shortly after classes began, he became disillusioned with the school and dropped out of his program of study. Although he immediately notified the school of his decision, he was reported as being in default for the full amount of the loan. He subsequently attempted to correct the situation, but was unable to do so, and when he attempted to enroll in a community college in another State several years later, he was denied financial aid because of his default status.

When school officials are asked to explain their failure to pay the required refunds, they generally refer to insufficient resources, administrative error, or a combination of those. The underlying causes that we have found for such failure, though, range from incompetence and faulty administrative procedures on the one hand, to outright fraud on the other.

As a result of one investigation, we found that a correspondence truck-driving school headquartered in Delaware had failed to refund about \$24 million for students who had dropped out of their training programs. Thus far, through the course of the investigation and a successful civil fraud suit we brought against the owners, the school has repaid about \$18 million and will repay an additional \$6 million. In this case, the school had for several years falsified computer records to hide its nonpayment of refunds.

Through another investigation, we found that from 1987 through 1990, a proprietary school in California offering a variety of vocational programs, including medical technology and security guard training, had failed to pay over \$6.4 million in refunds to about 2,500 students. During that same period, the school owner used about \$6.5 million in school funds to purchase seven real estate properties, sustain a lavish lifestyle of foreign travel, and purchase expensive jewelry and automobiles and make other personal investments.

We also have found that some lenders fail to properly account for refunds that they do receive, and the net result for the student borrower and the taxpayer is the same as that of a school's failure to pay a refund.

At this time, the Department relies on program reviews and audits to detect refund problems, and for a number of reasons these tools are not adequate for the task. Data is not available to estimate the total scope of the refund problem with much accuracy. However, we can safely say that the refunds that have gone unpaid since these programs were created amounts to millions of dollars. Refund problems were identified in at least 400 different program reviews and audits conducted in 1992-93 award years, and we have no reason to believe that the problem was less prevalent in prior years.

For six specific cases that I described in my detailed report, the refund liabilities amount to over \$37 million. While the liabilities assessed in most refund cases are smaller than in these examples, it is not at all unusual for a school to owe more than \$100,000 in unpaid refunds.

The case I have cited involving the correspondence truck-driving school with the \$24 million refund liability is atypical in that we were able to recover most of the amount owed through a multi-million dollar civil fraud suit, a prejudgment attachment of assets, and a measure of good luck. Normally schools with large refund liabilities are or become financially incapable of paying the money owed.

While the cost to the taxpayer from this type of program abuse is enormous, the greatest cost by far is the loss of hope in the disadvantaged youth for whom these Federal programs were created. It is particularly disheartening to know that this tragedy is continuing in spite of all that has been done thus far to reform the title IV programs.

I am aware of nothing in the design of the new direct loan program that will address this problem of unpaid or untimely loan refunds. Thus, the refund problem will likely continue as we move to direct lending and, in fact, the problem could worsen. Based on our experience in this area, there are several legislative and administrative recommendations that I would like to offer.

First, requiring participating schools to report, at least on a yearly basis, their current title IV refund liabilities, and to certify the accuracy of the reports. It would place the Department in a much better position to target its resources on schools that have large refund deficiencies, would serve as an incentive to the institutions to keep up with their refund obligations, and would greatly facilitate criminal and civil fraud prosecution.

The marginal additional burden on a school, which already should be keeping account of its refunds to be certified as administratively capable of participating in the title IV programs, is far outweighed by the enormous burden on students and taxpayers when refund problems are neglected.

Second, an aberrational ninth circuit Federal court of appeals decision, *United States v. Weincoup*, held that school employees and, by extension, schools and their owners, cannot be prosecuted for program fraud under 18 U.S.C. 666 because the schools are only indirect beneficiaries of Federal program funds under title IV. It has particularly negative ramifications for our use of asset forfeiture, since title 18 United States Code is an appropriate predicate for forfeiture in many of our cases. I recommend that section 666

be amended to clarify that those who benefit directly or indirectly from Federal programs may be prosecuted for program fraud.

Third, there are particular problems in reaching the assets of school owners where, as is often the case, the corporate school entity has been stripped of its assets. The Department should be authorized to obtain personal guarantees for title IV liabilities from school owners, or other appropriate persons, as a condition for participating in the title IV programs. Both the House and the Senate reauthorization bills contained such a provision. However, the conference committee amended the provisions to effectively nullify this authority. I recommend that the law be amended to remove the qualifying language.

Fourth, perpetrators of refund fraud often use these illegally obtained educational program funds to purchase real estate, cars, boats, jewelry, bank notes, and other personal assets. Recognizing the potential to recoup these ill-gotten gains, we recently began using the asset forfeiture laws. Indeed, in the case of California that I spoke about a moment ago, we were able to seize about \$4.6 million in real property.

The pictures that you see here, Mr. Chairman, are examples of that \$4.6 million in property. You can see the personal residence on the left there, with the \$650,000 estimated value, that we seized, and on the right a private investment residential property estimated at \$1,050,000.

I might also add, Mr. Chairman, that this institution had a default rate greater than 55 percent. Two statutory changes would greatly enhance our now limited ability to use asset forfeiture effectively. The first is full law enforcement authority which would facilitate the investigation of these cases. At present, OIG agents must request special deputation from the Justice Department on a case-by-case basis, a process we have found to be cumbersome and time consuming. Our only other option is to enlist the aid of another law enforcement agency with full law enforcement authority. This is also cumbersome and wasteful.

The second needed authority is forfeiture authority. Currently, the OIG has to enlist the aid of law enforcement agencies that have forfeiture authority. This is a waste of Federal law enforcement resources and can cause delays that allow the hiding and dissipation of assets. The Office of Inspector General also needs a statutory forfeiture fund so that it can share equitably in the proceeds of the assets seized to finance the OIG's law enforcement activities, quite similar to the suggestion that you made to my friend and colleague, Chuck Masten, a moment ago.

PREPARED STATEMENT

The fifth recommendation I would have is for administrative relief for student victims. In the 1992 HEA reauthorization legislation, Congress focused on the plight of some student victims of title IV fraud and abuse by requiring the Department to promulgate regulations to discharge the loan obligation of a student who is enrolled in a school that has closed or whose eligibility to borrow has been falsely certified by the school. Unfortunately, victims of fraud and abuse are not covered by this discharge provision. I recommend that this be resolved by legislative action.

Mr. Chairman, that concludes my summary, and I would be happy to attempt to respond to questions.
[The statement follows:]

STATEMENT OF JAMES B. THOMAS, JR.

Mr. Chairman, members of the subcommittee, I am pleased to be here today to share with the Subcommittee experiences of the Office of Inspector General concerning some of the most serious examples of abuse and fraud in the programs administered by the U.S. Department of Education [ED]. In line with the Subcommittee's request, I will focus primarily on the failure by many schools to pay required refunds on Federal student loans authorized under Title IV of the Higher Education Act [HEA]. I will also discuss two additional topics identified by the Subcommittee: our experiences regarding failure on the part of lenders participating in the Title IV programs to pay loan origination fees to the Department and problems associated with collection of disallowed overhead costs from grants and contracts.

BACKGROUND OF THE REFUND ISSUE IN THE CONTEXT OF HEA REAUTHORIZATION

Over the past several years, our office has devoted extensive resources to examination of systemic weaknesses plaguing Federal student financial aid programs administered by the ED. Beginning with my testimony at appropriation hearings in 1991, our office made 26 recommendations for changes to the HEA, most of which were adopted in legislative amendments in 1992 and 1993. I believe that these legislative changes, particularly those aimed at strengthening institutional eligibility requirements and procedures, did indeed lay the foundation for fundamental and far-reaching reform of the student aid programs. As the Department now completes its work of developing the regulations needed to implement the new legislation, our office is beginning its work of overseeing and documenting the results of this long process of reform.

Regarding the matter of loan refunds, however, a critical need for additional "fixes" remains. Students, at this moment, are being victimized by schools' failure to pay loan refunds when they withdraw from school during the period for which the loan was made; and when loan defaults result, the taxpayer is victimized as well. By failing to pay refunds, the school is keeping money it has not earned, for services it has not rendered. If done intentionally, this amounts to theft of public funds for which the borrower, although not at fault in any way, is left "holding the bag." This is a problem, then, of which the student borrower becomes directly and very painfully aware, but which is difficult to detect before it has seriously harmed both the student and the taxpayer. While high percentages of audits, investigations, and departmental program reviews identify failure of schools to pay required refunds, the Department has been ineffective in correcting the problem.

The main purpose of my comments today is to detail the nature of the refund problem and offer suggestions for addressing it. Improvements I will suggest to you include legislative changes to strengthen criminal penalties for refund abuse, to require necessary reporting and certification of refund liabilities by schools, and to provide law enforcement and asset forfeiture authority adequate to protect the financial interests of students and taxpayers. I will also offer for your consideration measures to provide relief for students who are so frequently harmed by schools' failure to pay loan refunds.

Before doing so, I would like to review with you the way the system should work: How the loans are made to students; and how, when, and to whom schools are required to refund the amount from those loans that they have not earned, and are not rightfully and lawfully entitled to keep.

HOW THE LOAN PROGRAM SHOULD WORK

The FFEL Program, formerly the Guaranteed Student Loan Program, was authorized by the Higher Education Act of 1965. It provides for the making of loans to undergraduate, graduate, and professional students to help them pay the costs of attending postsecondary institutions. Through PLUS loans, the program also provides assistance to the parents of dependent undergraduate students to help them contribute financially to the postsecondary education of their children.

To administer the FFEL Program, the Department relies on a multitude of outside entities. These entities include 46 State and private nonprofit guarantee agencies, approximately 7,800 commercial lenders, approximately 8,000 participating postsecondary schools, and various third-party servicers, secondary markets, and debt collection agencies.

The nature of the program is that commercial lenders loan their own funds to eligible borrowers. The loans are guaranteed against loss by guarantee agencies; and these guarantees are, in turn, reinsured by the Department of Education. Lenders receive interest subsidies based on quarterly Treasury Bill rates and, when interest rates are high, special allowance payments to further subsidize the low interest rates they are allowed to charge on the loans. Lenders may receive special allowance benefits for PLUS loans but are not eligible for interest benefits for these loans.

Students entering or attending eligible schools complete a portion of the loan application with the assistance of the school financial aid office. The application is then sent to the lender, who completes another portion. Finally, it is submitted to the guarantee agency, which approves and guarantees the loan. Upon notification that the application has been approved, the lender issues a loan check that is payable to the school and the borrower. The school, then, credits the borrower's account with the amount from the loan proceeds that are needed to pay for tuition and any other institutional charges, and the remainder is given to the borrower to pay for other educational expenses.

When a borrower fails to matriculate in or complete the instructional period for which the loan has been approved, the school is required to refund to the lender the unearned portion of the loan proceeds. The amount refunded is based on the school's refund policy, which must accord with the requirements of its State licensing board, its accrediting agency, or Federal regulations, depending on which provides for the largest refund. The refunds must be made within 60 days after a borrower's last day of attendance.

PROBLEMS IN THE ADMINISTRATION OF THE REFUND PROVISIONS

The major problem in the administration of the HEA refund provisions is that many schools fail to pay the refunds they owe to lenders. The result is that the borrowers often are incapable or unwilling to pay for services they did not receive, and their loans go into default. While the Federal Government, and ultimately the taxpayer, pick up the tab for default claims by the guarantee agencies, and for interest and special allowance payments to the lenders and secondary markets, the student borrower is held responsible not only for the entire amount of the loan but for accrued interest and for collection costs that can be charged by the lender and the guarantee agency. The total amount owed by the defaulted borrower frequently accumulates to more than twice the original loan amount.

Permit me to use a fictional example to explain the problem in greater detail. As is typically the case, Jane Doe is from an economically and educationally disadvantaged background and wants to better her life by returning to school. She decides to enroll in a vocational school and discovers that she would be able to do so with the help of a \$2,500 Federal loan. Because of personal problems, she decides to withdraw after attending classes for three days and so notifies the appropriate school officials. According to the school's refund policy, it is required to refund \$1,700 to Jane's lender. However, it fails to do so; and Jane is notified by the lender that she must repay the full \$2,500, instead of the \$800 that is rightfully hers to pay. After increasing harassment by collectors, she eventually is told that, with capitalized interest and collection charges, she must pay \$6,000 for the 3 days of instruction she received.

While she still has the low-paying job she had when she enrolled in the vocational school, her financial situation is significantly worse because her wages are being garnished and income tax refunds owed to her have been attached through IRS offset procedures. She also learns that, because of her defaulted loan, she is ineligible for the Federal student aid she needs to pursue her educational goals, and has been given a credit rating that will prevent her from obtaining a commercial loan for additional education or for any other purpose. She feels that her dreams for a better life have been destroyed by the very educational, financial, and governmental systems that had offered her deliverance.

Our investigators and auditors hear again and again of this kind of injustice perpetrated on student borrowers because of school failures to pay refunds. One such case involved a disabled Vietnam veteran who, with the help of a Federal loan of about \$2,500, enrolled in a proprietary business school in Illinois. Shortly after classes began, he became disillusioned with the school and dropped out of his program of study. Although he immediately notified the school of his decision, he was reported as being in default for the full amount of his loan. He subsequently attempted to correct the situation but was unable to do so; and when he attempted to enroll in a community college in another State several years later, he was denied financial aid because of his default status.

When school officials are asked to explain their failure to pay required refunds, they generally refer to insufficient resources, administrative error, or a combination of the two. The underlying causes for such a failure, though, range from incompetence and faulty administrative procedures on the one hand, to outright fraud on the other. The following cases, which we discovered through our audit and investigative activities, illustrate the problem:

- As a result of an investigation, we found that a correspondence truck-driving school headquartered in Delaware had failed to refund about \$24 million for students who had dropped out of their training programs. Thus far, through the course of the investigation and a successful civil fraud suit we brought against the owners, the school has repaid about \$18 million and will repay an additional \$6 million. In this case, the school had, for several years falsified computer records to hide its non-payment of refunds.
- Through another investigation we found that, from 1987 through 1990, a proprietary school in California offering a variety of vocational programs including medical technology and security guard training had failed to pay over \$6.4 million in refunds for about 2,500 students. During that same period, the school owner used about \$6.5 million in school funds to purchase 7 real estate properties, sustain a lavish lifestyle of foreign travel, purchase expensive jewelry and automobiles, and make other personal investments.
- In 1990 we conducted an audit of a chain of 17 proprietary schools headquartered in Texas that primarily offered training programs in electronics. By August 1990, it had closed the last of its schools and filed for bankruptcy. While the amount of refunds owed for the nearly 3,000 students who were "locked out" at the time of closure is not known, the schools owed about \$2.5 million in unpaid refunds for almost 3,000 students who had already withdrawn from their training programs. School officials claimed that they were not able to pay refunds because of a lack of financial resources. Yet, the school's president and vice-president, who were also its principal stockholders, received their usual annual compensation, which amounted to a total of \$356,000 and, in addition, had their expenses covered for such items as corporate retreats to Hawaii, rental of a football stadium suite, and costs associated with other business ventures. They also netted approximately \$1.1 million by transferring one of the school buildings to a real estate partnership they had created. As a result of the OIG audit, the Department established a total liability of \$3.1 million for the school, and subsequently filed a claim for that amount with the bankruptcy court.
- In a similar case, subsequent to an OIG audit in 1989, the corporate shareholders of a proprietary business school chain headquartered in Louisiana closed the last of its nine locations and filed for bankruptcy. Again, the amount of refunds owed to the 1,400 students who were enrolled at the time the school closed is unknown, but a year earlier they had owed nearly \$1.4 million in unpaid refunds for more than 1,000 students. During the 22 month period ending in August 1989, the principal shareholder and her daughter, the school president, received compensation amounting to more than \$1.3 million. In addition, the president transferred nearly \$500 thousand to another school she owned, which also participated in Title IV programs and owed refunds when it closed and filed for bankruptcy. As a result of the OIG audit, the Department established a total liability of \$1.4 million for the Louisiana business school chain, and subsequently filed a claim for that amount with the bankruptcy court.
- From 1987 through 1991, a chain of 5 proprietary schools headquartered in California and offering a variety of programs including computer training, medical technology, and security guard training failed to refund over \$2 million for 856 students. During this time, in spite of outstanding refund liabilities, the school owner drew over \$3.4 million from the school in loans to herself, and received numerous direct payments to cover personal expenses.
- From 1984 through 1987, a proprietary business school in Illinois (to which I have just referred in the case of the disabled veteran) failed to pay approximately \$1.3 million in refunds for over 900 students. The owner and an administrative official of the school were found to have used the money for such things as the purchase of a Mercedes and a yacht, re-decorating the owner's home, and gifts to the owner's girl friend. In September 1991, they were convicted of fraud, ordered to make restitution of over \$1 million, and sentenced to periods of imprisonment.

Another type of problem associated with refunds has to do with the lenders and their handling of the refunds they receive from schools. We have found that some lenders fail to properly account for the refunds, and in cases where they have sold the loan to a secondary market, fail to forward the refund to the new holder of the

loan. For example, in the late 1980's a major lender to Title IV students in California often sold its loans to a secondary market just after the first disbursement and then failed to forward to the new holder the amounts of the loans refunded by the schools.

In such cases the net result for the student borrower and the taxpayer is the same as that of a school's failure to repay a refund. The only difference is in who pockets the money at the expense of the student and taxpayer: in the first case, it's the school; and in the second, the lender.

THE DEPARTMENT'S RESPONSE TO THE REFUND ISSUE

Another aspect of the refund problem involves the Department of Education, whose efforts both to detect and remedy refund failures we have found to be ineffective. At this time, the Department relies on program reviews and audits to detect refund problems; and, for a number of reasons, these tools are not adequate for the task.

Since all schools participating in the Title IV programs are now required to arrange for non-Federal financial and compliance audits of their operations on an annual basis, these audits would appear to provide a good "early warning" system. However, schools often fail to have these audits performed; and the Department's efforts to enforce the audit requirement have been ineffective. (Since 1985, we have brought this problem to the Department's attention in two audit reports and two additional, management reports; but little has been done in response to our recommendations.) Even when these audits are performed, they are of limited value in quantifying refund problems because they are based on school records, which are often inaccurate, and on a required minimum sample size of only 50 students. In addition, it is difficult and costly for auditors to extrapolate from the samples studied to account for the total number of student borrowers. In most cases, program reviews conducted by the Department of Education are also limited to small samples, and are, of course, performed much less frequently than non-Federal audits.

Because of these limitations, and the state of the Department's information systems, data is not available to estimate the total scope of the refund problem with much accuracy. However, we can safely say that the refunds that have gone unpaid since these loan programs were created amount to several hundreds of millions of dollars. We make this claim based on three general indicators. First, regional OIG staff report to us that the failure by schools to pay required refunds is the most common problem with which they have had to deal, and that they have fielded hundreds of calls by desperate borrowers who claim to have had their lives ruined by the default problems that result from this failure by schools. Second, we have been able to determine that refund problems were identified in at least 400 program reviews and audits conducted during the 1992 and 1993 award years, and we have no reason to believe that the problem was less prevalent in prior years. Third, we know that large amounts of money are involved. For example, the cumulative known refund liability of the six schools in the specific cases I have just described amounts to over \$37 million. While the liabilities assessed in most refund cases are smaller than in these examples, it is not at all unusual for a school to owe more than \$100 thousand in unpaid refunds.

The case I have cited involving the correspondence truck driving school with the \$24 million refund liability is atypical in that we were able to recover most of the amount owed through a multi-million dollar civil fraud suit, a prejudgment attachment of assets, and a measure of good luck. The amount recovered in most cases is but a fraction of this. Normally schools with large refund liabilities are or become financially incapable of repaying the money owed. In some of these cases, the Department has negotiated repayment agreements under which schools are given several years to repay, which amounts to an interest free loan to the very people who are ultimately responsible for the harassment students receive from lenders and collection agencies to pay substantial interest and collection charges. Certainly in the eyes of the students victimized in this process, the Federal Government must appear to be on the side of the victimizer.

While the cost to the taxpayer from this type of program abuse is enormous, the greatest cost, by far, is the loss of hope in the disadvantaged youth for whom these Federal programs were created. It is particularly disheartening to know that this tragedy is continuing in spite of all that has been done thus far to reform the Title IV programs.

While I am in agreement with those who believe that the new Direct Loan Programs, if adequately supported and properly implemented, will achieve economy and efficiency in the administration of Federal student loans over the long run, I am aware of nothing in the design of the new loan programs that will address the prob-

lem of unpaid or untimely loan refunds. Participating schools will continue to be responsible for calculating and paying refunds under direct lending. They will continue to manage loan funds on behalf of students and will continue to record student withdrawal dates in order to calculate and pay refunds. And whether or not the refunds are accurately calculated and actually paid will still depend on the honesty of school officials, the accuracy of their records, and the adequacy of their administrative practices.

Thus, the refund problem will likely continue as we move to direct lending. In fact, the problem could worsen as the new loan programs are implemented and the structures now in place for administering Guaranteed Student Loans are phased out. As the banks and guarantee agencies are phased out of the Federal student lending process, the degree of oversight they have provided, under the guaranteed loan programs, will be lost, and the incentives for them to diligently manage their guaranteed loan portfolios will diminish.

CORRECTING THE PROBLEM

The amendments to the HEA that were enacted in 1992 will help in addressing the refund problem but will not solve it. Changes requiring closer oversight of participating schools by the Department and newly created State Postsecondary Review Entities should put schools on notice that their performance in paying refunds will be monitored. However, given the difficulty the Department has had in recognizing refund problems before huge monetary liabilities accumulate and the demonstrated capability of schools to "hide" their failure to pay refunds, the new oversight provisions will not end this kind of program abuse.

Other provisions of the 1992 amendments require schools to maintain at all times cash reserves for the purpose of paying refunds, and submit to the Department audited financial statements on an annual basis. However, although these provisions are a good step toward improving the identification of refund deficiencies, they both can be circumvented by schools. For example, if a school fails to appropriately record student withdrawals and appropriately compute refunds, its financial statements will not accurately reflect the refund amounts it is required to pay. Since these refund amounts are the basis for computing its required cash reserve for the subsequent year, the school's erroneous record-keeping and refund calculations will have limited the effectiveness of both of the new provisions.

There are several problems that must be addressed if we are to effectively detect and prevent refund abuse. In addition, there are legal and practical obstacles associated with the criminal and civil cases resulting from this abuse, and such cases are very resource-intensive. Based on our experience in this area, there are several legislative and administrative recommendations that I would like to offer at this time.

Refund status reporting.—It is axiomatic that if you don't know a problem exists you can't fix it. Since the Department does not collect data on the loan refund status of schools that participate in the Title IV programs, it has no way of knowing if a refund problem may exist at any particular school. We recommended to the Department in a March 1992 Management Improvement Report [MIR] that it require participating schools to report, at least on a yearly basis, their current Title IV refund liabilities and to certify the accuracy of the reports (MIR 92-06). This recommendation followed informal suggestions to this effect as well as recommendations on the refund problem in a 1990 audit report.

To date, the Department has not implemented our recommendation, based on the rationale that annual audit reports by non-Federal auditors are sufficient. We strongly disagree. As I have just discussed, these audit reports provide no basis for quantifying a school's outstanding refund obligations. At most, they may indicate that a school has failed, in some cases, to make required refunds. If the Department investigates the matter further, it is not uncommon for the school to deny that it has a general problem with refunds. The result is that refund deficiencies often get out of hand before the Department can take appropriate action.

A regular reporting cycle, with the appropriate certification requirement, would place the Department in a much better position to target its resources on schools that have large refund deficiencies. Moreover, such a reporting requirement would serve as an incentive to institutions to keep up with their refund obligations. Creating such an incentive is particularly important because enforcement in this area is currently so lax that many schools do not take their refund obligations seriously.

Of importance to the OIG, such a report would greatly facilitate criminal and civil fraud prosecution and is sorely needed in view of the problems we have had in prosecuting refund cases, as I will presently discuss. If a school owner or administrator knowingly certifies falsely as to an institution's refund liability, and its future receipt of Title IV funds is conditioned on the accuracy of the information reported,

then we have a straight-forward false statement case and a manageable civil fraud case. I submit that this is one simple fix to a very troublesome problem. The marginal additional burden on a school, which already should be keeping account of its refunds to be certified as administratively capable of participating in the Title IV programs, is far outweighed by the enormous burden on students and taxpayers when refund problems are neglected.

Criminal prosecution.—It has proven problematic to address refunds through criminal prosecution because some prosecutors and courts have viewed the failure to pay refunds as solely a civil and not a criminal matter. We are optimistic that the Senate-initiated amendment in the reauthorized HEA that specifically targets the failure to pay refunds as a separate criminal violation (20 U.S.C. § 1097) will solve this problem in most cases.

A legislative change that would be of significant help to us in prosecuting fraud cases in general would be an amendment to the program fraud statute 18 U.S.C. § 666 to reverse the effect of an aberrational Ninth Circuit Federal Court of Appeals decision, *United States v. Wyncoop*, 11 F.3d 119 (9th Cir. 1993). In this case the Court held that school employees (and, by extension, schools and their owners) cannot be prosecuted for program fraud under this statute because the schools are only indirect beneficiaries of Federal program funds under Title IV, and only direct beneficiaries (students and lenders) can be prosecuted under section 666.

Although this court-imposed distinction between direct and indirect beneficiaries of Federal program funds is found nowhere in the anti-fraud law itself, it undercuts our efforts to go after the big fish and not just the small fry, not only in refund fraud cases but in cases involving other types of program fraud as well. It has particularly negative ramifications for our use of asset forfeiture, since 18 U.S.C. § 666 is an appropriate predicate for forfeiture in many of our cases. Because of this, I recommend that section 666 be amended to clarify that those who benefit directly or indirectly from Federal programs may be prosecuted for program fraud. I will elaborate further on the issue of asset forfeiture later in this testimony.

Civil remedies.—It may sound simple to sue a school or school owner for payment of unpaid refunds, but we have found such cases very difficult and resource-intensive. There are particular problems in reaching the assets of school owners where, as is often the case, the corporate school entity has been stripped of assets. There are also major problems in calculating unpaid refunds of federally insured loan funds, because we must rely on school records which are often incomplete, unauditable, or falsified. The Government's damages must then be calculated, indirectly, based on the defaults that have resulted from the unpaid refunds. Also, prosecuting such civil cases can take years, while the student borrowers and the Department are left to deal with the consequences of the schools' failure to pay refunds and those responsible for that failure enjoy the benefits of the unpaid refunds.

On the brighter side, a notable success is the recent settlement of a civil fraud case we brought against a Delaware truck-driving school, which I just discussed in some detail. To achieve that successful conclusion, however, we had to devote a substantial portion of our audit and investigative resources. Also critical to our success was our ability to have pre-judgment liens placed on the school owners' property, which is possible in only limited circumstances under Federal law.

The only remedy we know of that would significantly affect this situation is one that we recommended as part of the 1992 reauthorization of the HEA: the Department should be authorized to obtain personal guarantees for Title IV liabilities from school owners or other appropriate persons as a condition for participating in Title IV programs. Both the House and Senate reauthorization bills contained such a provision. However, the Conference Committee amended the provision to effectively nullify this authority. Section 498(e)(4) of the new law bars the Secretary from imposing personal liability unless the school meets all four of the following conditions: it has been subject to limitation, suspension, or termination action within the last 5 years; it has had recent audit findings that required it to make substantial repayment; it is not financially responsible; and it is not current in submission of required audit reports. It is extremely unlikely that a school would meet all of these conditions, since, long before doing so, it would certainly have been closed and gone into bankruptcy, and its owners, taken off with the money.

I recommend, therefore, that the law be amended to remove the qualifying language added by the Conference Committee. Without such an amendment, the personal liability provision is virtually meaningless.

Asset forfeiture and full law enforcement authority.—Fraud against HEA programs often runs into millions of dollars. Perpetrators of such fraud consistently use these illegally obtained education program funds to purchase real estate, cars, boats, jewelry, bank notes, and other personal assets. Recognizing the potential to recoup these ill-gotten gains, we recently began using asset forfeiture laws (particularly 18

U.S.C. §§981 (civil) and 982 (criminal)) in the investigation and prosecution of our cases. To date, we have conducted investigations involving the prosecution of trade school owners that have led to the civil seizure and forfeiture of over \$10 million, including \$4.6 million of real property in California, real estate properties and \$70,000 cash in Puerto Rico, and expensive computer equipment in Louisiana.

Two statutory changes would greatly enhance our now limited ability to use asset forfeiture effectively as a tool for addressing student aid fraud: (1) full law enforcement authority for OIG special agents, and (2) forfeiture authority.

Full law enforcement authority—the authority to make arrests, swear out warrants, and carry weapons—would enable OIG agents to execute affidavits for warrants necessary for the successful investigation of asset forfeiture cases involving student aid fraud. It would also facilitate the investigation of cases requiring work in high-crime urban areas. Many of our educational fraud cases, including those involving the failure to pay refunds, involve trade schools located in or recruiting from such areas; many such schools recruit students from drug rehabilitation centers, homeless shelters, blood donor centers, and the like. At present, OIG agents must request special deputation from the Justice Department on a case-by-case basis, a process we have found to be cumbersome and time-consuming. Our only other option is to enlist the aid of another law enforcement agency with full law enforcement authority. This is also cumbersome and wasteful of federal law enforcement resources. The delay associated with deputation and obtaining assistance from other agencies is especially burdensome in asset forfeiture cases, because delays can result in the loss, dissipation and/or removal of assets.

Forfeiture authority—the authority to seize and dispose of assets that are the proceeds of certain unlawful activity—would allow for OIG agents to independently prepare cases for asset forfeiture. Currently, OIG has to enlist the aid of law enforcement agencies that have forfeiture authority, and this is a waste of federal law enforcement resources and can cause delays that allow the hiding or dissipation of assets. OIG also needs a statutory forfeiture fund, so that it can share equitably in the proceeds of the assets seized to finance the OIG's law enforcement activities. Forfeited assets now go into the asset forfeiture funds of other agencies (e.g., Department of Justice, Treasury, Postal Service), and OIG cannot share in the cash proceeds of the assets forfeited as a result of its efforts on educational fraud cases. OIG would like to be placed in at least the same position as state law enforcement agencies that can, under Federal law, claim and receive an equitable share of the cash proceeds of forfeited assets for their assistance with asset forfeiture cases. These cases are resource-intensive and require highly trained staff; they require extraordinary expenditures, such as for title searches and asset-locating data bases. OIG's investigative work should be funded in part from the proceeds of asset seizures.

Administrative relief for student victims.—In the 1992 HEA reauthorization legislation, Congress focused on the plight of some student victims of Title IV fraud and abuse by requiring the Department to promulgate regulations to discharge the loan obligation of a student who is enrolled in a school that has closed or whose eligibility to borrow has been falsely certified by the school. Unfortunately, victims of refund abuse are not covered by this discharge provision. The OIG, in the course of discussing the 1992 discharge provision with the Department, pointed out that refund victims are a group worthy of discharge relief because they are asked to repay loans for services they never received and because the Department has not been successful in enforcing the refund obligations of schools. Because of the magnitude and complexity of this problem, I recommend that it be resolved by legislative action.

FAILURE OF LENDERS TO PAY REQUIRED LOAN ORIGINATION FEES

Mr. Chairman, you asked me to also discuss reports that lenders sometimes sell loans before paying the related origination fees and, as a result, the Department may not be receiving millions of dollars owed by lenders.

We identified deficiencies in the Department's process for collecting loan origination fees as far back as 1989. We issued a Management Improvement Report in February 1990 recommending corrective actions to identify lenders that may owe origination fees and reduce interest costs to the Department. In July 1992, the General Accounting Office [GAO] reported the same problem and recommended additional corrective actions.

Background.—When a lender originates a loan under the FFEL Programs, there is an origination fee of 3 percent of the principal amount of the loan that must be submitted to the Department. Through fiscal year 1989, lenders were permitted to submit billings for their interest subsidies (Form 799) on a quarterly, semiannual,

or annual basis. Beginning with the quarter ended December 31, 1989, lenders have had to submit the Form 799 on a quarterly basis. Lenders offset the origination fees due to the Department with the interest subsidies due from the Department on these forms. Since the interest subsidies are generally greater, the lenders usually do not send payments to the Department for the origination fees.

Occasionally, in the case of a lender that sells its loans shortly after origination, the origination fees are greater than the interest subsidies. In these cases, the Department will create a receivable due from the lender and initiate appropriate collection, unless the lender submits a payment along with the Form 799.

Deficiencies.—Although lenders are now required to submit the Form 799 on a quarterly basis, the Department does not have an adequate internal control system to track the submission of the Forms 799 to identify lenders that fail to submit. Lenders that owe origination fees and do not submit the Form 799 prohibit the Department from establishing a receivable and initiating collection efforts.

These lenders improperly retain the origination fees resulting in additional interest costs to the Department. Furthermore, if a lender becomes insolvent owing origination fees, the collection becomes more difficult.

In our Management Improvement Report, we provided two examples of lenders failing to submit their Forms 799 and the origination fees they owed. In one case, a bank in Kansas was identified, in 1988, as failing to submit Forms 799; and the amount of its unpaid origination fees had accumulated to \$4.4 million. While the bank eventually repaid the outstanding fees, the Department did not recover the resulting interest costs it had incurred, which amounted to about \$122,000.

In 1989, a trust company located in California was cited for its continued failure, since June 1987, to submit Forms 799. The amount of outstanding origination fees amounted to \$5.5 million when the State Banking Commission took control of the trust company in May 1989. In 1990 the Department entered into a settlement agreement with the State for approximately \$4.4 million. The interest costs incurred by the Department was over \$550,000.

What we recommended.—To identify lenders not paying origination fees in a timely manner, we made the following three recommendations: (1) the Department should require each lender participating in the FFEL Programs to submit the Forms 799 each quarter whether or not interest subsidies are due; (2) the Department should establish a system of internal controls to assure that all Forms 799 are received in a timely manner; and (3) the Department should initiate prompt action when lenders fail to submit the required reports.

Corrective actions taken.—The Department issued a Dear Colleague Letter in October 1991 to the chief executive officers of all lenders summarizing their responsibility to promptly pay origination fees and the consequences of failure to remit the fees.

The Department also established an internal control in the Interest and Special Allowance (ISA) system to identify lenders that do not submit Forms 799 for four consecutive quarters. These lenders are then rendered inactive in the ISA system.

Current status.—GAO's audit of fiscal year 1992 financial statements for the FFEL Programs and our ongoing joint audit with GAO of the fiscal year 1993 financial statements have both identified the failure to timely submit origination fees as a deficiency.

The Department's internal control to identify lenders not submitting the Forms 799 for four consecutive quarters is inadequate. This control only identifies lenders not submitting the Form 799 and is not capable of determining if the lender was originating loans during this period. If the lender was originating loans, the interest costs to the Department due to the lender's failure to submit the originating fees is unknown.

Planned corrective action.—The Department will be relying on the National Student Loan Data System [NSLDS] to identify lenders originating loans and not submitting the Forms 799. The NSLDS, scheduled to be operational later this year, will be an on-line database to store data on each loan guaranteed and segregating the loans by lender. This information can be matched against the ISA system to determine if all lenders originating loans are submitting the Forms 799.

With the implementation of the Federal Direct Loan Program beginning in July of this year, participation in the FFEL Programs will continue to decrease over the next five years. Because of this, the problem of nonpayment of loan origination fees should diminish in future years.

DISALLOWED OVERHEAD COSTS

Finally, Mr. Chairman, I would like to address the third issue raised by the Subcommittee, that being problems related to disallowed overhead costs from grants

and contracts. For several reasons, which I will outline for you now, the Department of Education has not experienced the same problems in this area as have other agencies.

The main reason such problems have not arisen for the Department of Education is that it does not have the same degree of responsibility for administering overhead cost provisions as do other agencies. Under these provisions, the Department of Health and Human Services [HHS] and the Department of Defense [DOD] have responsibility for negotiating and administering overhead rates (also referred to as indirect cost rates) for the large majority of colleges and universities. In addition, HHS alone has responsibility for administering the overhead cost provisions for a large number of State and local governmental agencies. In this capacity, HHS and DOD are referred to as cognizant agencies for the institutions and agencies for which they are responsible. To the extent that problems with overhead cost allowances arise with these particular governmental and educational entities, they are resolved by their respective cognizant agencies, not by the Department of Education.

When a cognizant agency determines that overhead costs have been improperly charged to Federal programs and activities, the agency often "rolls forward" to future years the disallowed costs. For example, if the cognizant agency determines that the amount (or "pool") of overhead costs upon which a State agency's overhead rate has been established has included \$1 million in disallowed costs, the State agency's overhead cost pool for a subsequent year is reduced by \$1 million, which, in turn, reduces the rate the agency must use in that later year in billing the Federal Government for its overhead costs. In this way, the cognizant agency may "recover" misspent funds and yet avoid heavy collection costs.

Other factors that affect the magnitude of overhead cost problems for the Department of Education is that many of the programs it administers have specific limitations on the rates that may be established for recipient entities. For example, under the \$8 billion Chapter I Program, State Education Departments are restricted to charging no more than 8 percent for overhead costs. Similarly colleges and universities are limited to claiming no more than 8 percent under Education Department training grants. These limitations, in and of themselves, reduce the potential in Federal education programs for abuse of overhead cost provisions.

For the above reasons, we have not found that the Department of Education has had to deal with the same level of abuse of overhead cost allowances that other agencies may experience.

CONCLUSION

At the beginning of my testimony, Mr. Chairman, I stated that my primary purpose today was to detail problems associated in schools' failure to pay loan refunds and to offer suggestions to address these problems. I believe my comments have shown that there is probably no other aspect of the Federal Student Financial Assistance Programs that is, and without effective action is likely to remain, so injurious to students and taxpayers.

In addressing the problem of refund abuse, the Department and the Congress should bear in mind that the acronym, "SFA Programs," stands for the "Student Financial Assistance Programs" and not the "School Financial Assistance Programs." SFA funds are not intended to be used as interest-free loans or subsidies for cash-strapped schools or bonuses for school owners at student and taxpayer expense. Legislative changes need to be made, and procedures developed, to hold schools accountable for making accurate and timely refunds when students drop out, and to effectively deal with those who would steal Federal funds by intentionally failing to do so.

My office stands ready to assist the Subcommittee in any appropriate way as you seek to address this problem.

I will be happy now to respond to any questions you may have.

TRUCK-DRIVING SCHOOL

Senator HARKIN. Mr. Thomas, thank you very much for your diligence and for bringing this to our attention. Just going back to your testimony here, you talked about that truck-driving school in Delaware. You got the money back but, again, I ask were there any penalties involved in this or did they just have to pay back the money?

Mr. THOMAS. In this case, this was a civil suit that we brought against the school. In addition, they were convicted of crimes against the Government. So the two owners and two or three additional senior members of the organization were, in fact, convicted in criminal court. And through the civil suit, we were able to get both cash and property and some of that is still in liquidation at this point in time.

Senator HARKIN. But, again, you had to go through this lengthy process. Just out of curiosity, do you remember what year this started, how long you have been doing this?

Mr. THOMAS. It started in around 1989, as we remember. Senator, you are absolutely right in that it is not only a long time but it is extremely staff intensive. Within the OIG alone, we spent close to 20 staff years of effort, and with a criminal investigative staff of about 60 street agents, you cannot do terribly many cases. That, of course, included auditors as well as investigators. But in addition to that, it also included a number of IRS agents and FBI agents who assisted us at various times during the investigation. Very staff intensive.

Senator HARKIN. You mentioned about the problem likely to continue, and may even get worse, as we move to the direct loan program. Could you expand on that?

Mr. THOMAS. I did not mean to imply there, Senator, that the direct loan program itself would incur additional kinds of refunds, but rather as we move toward the direct lending, we are going to be moving away from lending by banks and other kinds of lending institutions. And as we do that, the amount of oversight that is now provided by guarantee agencies is probably going to go down, because we anticipate there to be consolidations of those organizations and some perhaps even going out of business. And as time goes on, there is going to be more and more time, I think, devoted toward the direct lending, and less and less time devoted toward following up on the old program. And we just see that as an added cause for this to happen.

And the additional reason is that as schools are moving into the direct lending program, they have to meet certain criteria established by the Department. And what that means is that these are real good schools that are coming in, ones whose default rates are low and ones which, in all likelihood, have had very few, if any, refund problems. And so the ones that remain outside that program are the ones that continue to have the high volume of refund problems.

Senator HARKIN. You have given us a number of suggestions here. Schools do not have to report on any kind of an annual basis now on their refund liabilities.

Mr. THOMAS. No, sir; there is no requirement for reporting on refund liabilities. The Department relies completely on what has been the biennial audit, which in the future will be an annual audit done by private CPA firms, and on program reviews performed by the Department. And, of course, those, the biennial audits are only on a test check basis where they look at a given number of transactions and in no way even attempt to quantify the total amount of refunds. The best you could hope to do would be to find that there are refunds due from the limited tests that are

made, and then that might instigate the Department to go out and do further review.

Senator HARKIN. I would also like to work with you and receive from you any suggestions for clarification of 18 U.S.C. 666.

Mr. THOMAS. We would be very happy to work with you on that, Mr. Chairman.

Senator HARKIN. I think that definitely needs to be changed.

Mr. THOMAS. I will have Counsel to the inspector general contact your office.

Senator HARKIN. I assume that that circuit court decision went no further than the circuit court.

Mr. THOMAS. The circuit court decision was in response to an appeal by the defendant. Justice refused to take it further, at this time, Mr. Chairman.

Senator HARKIN. It sounds like it is, again, something in the law that we have to change here.

Mr. THOMAS. That is correct, sir. We have a number of cases at this time in different jurisdictions, and we are working with the U.S. attorneys trying to continue prosecutions. Time will tell whether it will be carried over from one jurisdiction to another.

Senator HARKIN. Could you just give us some more details about the methods the school used to avoid paying refunds, the diversion of funds for personal use, and how your investigation led to a successful prosecution and recovery of funds? Just take one of the cases. I do not care which one. You can take this one, if you want.

Mr. THOMAS. Well, I think that one in Delaware is probably a little bit better example, because it was a little bit more clean cut and it kind of had the whole story in that we were able to get some money back and use it to pay off the refunds. What we found there was that the president of the company had actually set a dollar limit, that he would be willing to pay refunds up to this amount but not pay any refunds more than that amount. So there was an automatic withholding of refunds by decision.

Second, we found significant alteration of the records that were maintained there. And related to those alterations, we found that when we went in to do our audit, that the false records were submitted to us and were attested to us as being accurate, and as a consequence, one of the crimes that we were able to prosecute some of the people on, and they ultimately pled guilty, was on the interference with a Federal audit. And so by them submitting the false records, we were able to take appropriate criminal action based upon that.

As far as the way they took the money out, one of the ways was they would create separate corporate entities, and then take the profits that were being withheld by unpaid refunds and put them in those other corporations and purchase real estate with them. And these other entities also were owned by the same person and people that owned the school.

Once we presented ourselves and started getting into this case, we were lucky in that we found a number of insiders in the organization who were willing to testify, who were willing to work with us, and who were willing to help us identify where the falsification had been made in the records. And so that was the part that I alluded to in my testimony as being the good luck part. It is not al-

ways that you can find good inside witnesses that will help you like that.

We also, in this case, ran a parallel process where we had both the criminal investigation ongoing and the civil. And both were successful. We had successful prosecutions and findings of guilt. We had, also, a very successful criminal case in that the result was the returning of almost enough money to pay off all the refunds.

Senator HARKIN. Last, could you just tell me a little bit more about asset forfeiture? You made a strong argument for it in pursuing these perpetrators. How would it work? How would an asset forfeiture fund work?

Mr. THOMAS. Well, Mr. Chairman, at the present time—if you take these properties, for example. When we have a criminal case and certain levels of evidence are present, we go to the U.S. attorney, we go—at the present time we have to find another Federal law enforcement organization that would work with us, and we get the appropriate documents that would allow us to seize these properties. Once we seize them, they become, in essence, held by the Federal Government. At the present time the Marshal Service administers the assets.

Along the way there is due process allowed to the person from whom the assets were seized. Either that person has the option of doing something or not doing something originally. If he decides not to do anything within a given period of time, the assets become Federal property, and then the Marshal Service can dispose of them and use the funds for the Department of Justice law enforcement purposes.

Now, what we are proposing is that an asset forfeiture fund be created that would allow us, the Department of Education Inspector General's Office, to have a fund into which we would place some of the proceeds from forfeited assets to help pay for law enforcement activities. It would require an act of Congress to allow that kind of fund to be set up in the Department. It is not something that we can do administratively.

We do not have any particular desire to get into the asset management business, and so we would continue to work very closely with the Marshal Service or Postal Service or somebody else who does that at the present time. We do not have the staffing, first, to do it, nor would we want to allocate the present staff that we have to do that kind of activity.

That goes right along with our recommendation for full law enforcement authority. At the present time we have an agent go out and perform the very tedious job of tracing the flow of Federal funds that come into an institution to the use of the Federal money for personal purposes. This is the indirect use that we propose you amending section 666 to cover.

Once that money is traced flowing through to purchase this outside property and we do that with our agents, once we get to that point and we say well, now, can we seize that property, and we go to a magistrate or a court and try to work through the appropriate legal documentation, we have to stop.

We have to get a full law enforcement officer from some other agency, to come over and sign an affidavit. And so what we have to do, then, is sit down with another agent and explain to him ev-

everything we have been doing for the last 2 months, 6 months, or 3 years in this case. And that other agent has no first-hand knowledge of any of this stuff, so he is sticking his neck out or she is sticking her neck out by signing this affidavit. And it is based upon that affidavit that you get the seizure documents, and you go and present them and take over the property.

That is an extremely inefficient way to do business and a very ineffective way. One of the things, Mr. Chairman, that both the President and the Congress have seen fit to do recently is to increase the law enforcement expenditures out in the countryside. Well, there are those who say that these things that we deal with are white-collar crime and therefore, you know, anybody should be able to do it.

I would point out to you that many of the people that we deal with are not very nice folks. You know, we have been involved with street gangs and people who have had multiple convictions of murder and rape and robbery and the like. Many of the people that we deal with are economically and socially disadvantaged folks and live in very bad parts of town. Many of them are scamming the system, could even be contractors such as you heard my colleague explain a while ago, and the like.

And so every time I send an agent out, I pray that that agent will get home that night to his or her family safely, because they have no protection, they go out by themselves, and they are at risk all the time. And the first time one gets killed or wounded in the line of duty, I do not know whether I am going to pay or whether you are going to have to pay, Mr. Chairman, but somebody is going to have to pay that family.

It is not a very pretty sight today, and I think that if we do not get full law enforcement authority, we are really holding our people to an extreme disadvantage. And we are keeping law enforcement people off the streets. At the present time, for example, an FBI agent is involved in bank robberies and car thefts and all that kind of stuff, and we have to call them off of those kind of jobs to come over and sign these affidavits and help us go out and finish working this case.

And so on the one hand we say that we want more people on the street, to deal with street crime. On the other hand, we are not using effectively the agents that we already have trained, we already have in the system, in order to take care of these cases effectively. So I make a plea to you that you consider that.

Senator HARKIN. Very good. Well thank you again, Mr. Thomas, and I look forward to working with you on this, and especially getting that proposed language for a change in the section 666.

Mr. THOMAS. Thank you, sir.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much Mr. Thomas.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Question. You have urged us to strengthen the laws to facilitate criminal prosecution in cases involving refund fraud. Do you believe that criminal penalties are a greater deterrent to such fraud than the threat of civil suit?

Answer. In general, yes, because owners of schools that commit refund fraud perceive that, using resources obtained as a result of participation in Title IV programs, they can outlast and beat the government during the course of protracted civil litigation. Targets rightly perceive that it is more onerous for the government to prepare and bring civil cases and that they have more opportunity to derail the process.

It is harder to obtain evidence for use in civil proceedings than criminal; for example, IG administrative subpoenas often are harder and take more time to enforce than grand jury subpoenas. There are substantial legal obstacles posed by the Right to Financial Privacy Act to getting bank records from financial institutions on individuals with administrative subpoenas as opposed to grand jury subpoenas. In many cases, cooperation by witnesses necessary to a civil case is available only because of a parallel criminal case.

Undeniably, it is of paramount importance to recover money and assets from the wrongdoer and not just obtain a conviction and leave the wrongdoer with the fruits of his wrongdoing. We intend to work smarter by using all remedies—civil and criminal—available to us and appropriate to the case to bring this about and obtain the maximum deterrence.

Asset forfeiture, which deprives wrongdoers of the fruits of their refund fraud, is the greatest potential deterrent, and it is essentially a criminal remedy because there must be certain criminal activity present before forfeiture can take place. We want to use asset forfeiture more aggressively, as I have described in my testimony, and we intend to do so responsibly.

Question. You say in your testimony that the Department of Education relies on program reviews and audits to detect refund problems. How often does the Department conduct program reviews for institutions participating in the guaranteed student loan program?

Answer. We recently completed a performance audit of the Department's program review process, issued in December 1993. The statistics we gathered during this audit showed that during fiscal years 1990, 1991 and 1992, program reviews were performed at 1,117, 1,007 and 684 schools, respectively. The reason for the decrease in the number of reviews in 1992 was a result of an increase in the number of staff assigned to, and the duration of the reviews.

Question. Are these reviews targeted in any fashion?

Answer. The Department also utilizes a factor list to identify schools to be selected for review. These factors include default rates above 30 percent, overdue non-Federal audits, no review in the last four years, change of ownership, financial difficulties, and significant increases in funding. We made recommendations for the Department to improve its targeting of schools by including known areas of abuse as a high rating factor.

Question. When the Senate Permanent Subcommittee on Investigations held hearings on abuses in the Pell Grant program last fall, it discovered that proper administration of Pell Grants essentially rests on an "honor system," making the program an easy mark for those who are motivated by personal gain. Can the same be said of the refund situation in our student loan programs?

Answer. Yes, "honor system" is a very apt way to describe the refund system for the Title IV loan programs. As I detailed in my testimony, there is now no reporting of refund liabilities to the Department. Even when a problem is uncovered at a school, the Department relies on the school's records and has no independent process to ensure that the school is current in its refund obligations or even what the magnitude of the problem is. A good example is the case of Phillips Colleges mentioned in another of your questions. The Department has known since 1991 that Phillips has a refund problem, and the matter is still in dispute. After years of negotiation and litigation with PCI over this and related matters, the Secretary on April 29, 1994, allowed the school chain to remain in the Title IV programs with the proviso that Phillips "work cooperatively" with the Department "to identify and locate students to which Phillips still owes refunds, and expeditiously provide such refunds." This is the result of the "honor system" for refunds.

Question. Are there any procedural changes that would strengthen this system?

Answer. A regular reporting requirement for schools of their refund liability, certified correct by the owner or control person, would, as I have testified, be a procedural change that would strengthen this system. The Department has the opportunity now, with the designing of the Direct Loan Program, to address the refund problem and build safeguards into the system.

Question. Is failure to pay refunds one of the criteria that would trigger review of an institution by the new State Postsecondary Review Entities created by the Higher Education Amendments of 1992?

Answer. A school's failure to pay refunds is not specifically included as one of the criteria that will trigger review by the new State Postsecondary Review Entities [SPRE's]. However, a school that has significant refund problems may have problems in other areas that would trigger its selection for State review. The four criteria that may trigger such a review are the following:

- The school has received an audit finding in either its last Title IV non-Federal audit or the prior such audit that required repayment by the institution of an amount greater than 5 percent of the Title IV funds it received for either of the years covered by those audits;
- The school has been cited by the Secretary of Education for its failure to submit acceptable Title IV non-Federal audit reports by established deadlines;
- The school has failed to meet the Title IV financial responsibility standards; and
- The school has been subject to a pattern of student complaints that, in the Secretary's judgment, is sufficient to warrant State review.

We have considered whether a standard relating more directly to refund problems would be helpful and have concluded that, before recommending such a change, the Department and the States should be given time to implement the new review procedures and to evaluate their results. The final regulations on the State Postsecondary Review procedures were just recently published and have not been fully implemented.

Question. Failure to pay refunds often emerges in audits years before schools close down and leave students and taxpayers holding the bag. This suggests that early detection alone may not be sufficient to stop the refund problem. Are there any administrative controls that could be used to enforce compliance with refund requirements when problems are first detected? (For example, what does the Department do when a school simply denies that it has a refund problem?)

Answer. The Department does have several administrative controls to address refund problems at schools when they are first detected. However, each of these controls require extensive Departmental resources to enforce, resources which are not always available.

First, through the resolution of audits and program reviews the Department establishes school liabilities for unpaid refunds and accrued interest and special allowance. Collection efforts can then be initiated.

Second, the Department can require the school to post an irrevocable letter of credit or enter into an escrow agreement under which all loans flow through an independent escrow agent. Under this process the school should receive no loan proceeds until the funds are earned by the school.

Third, if the refund problem is serious, the Department can impose an emergency action or initiate termination proceedings to eliminate the school from the loan program.

Regarding the example you cited, it first would be incumbent upon the Department to assure itself through audit or program review that there is in fact a refund problem. When the Department has the documentation, it can initiate one or all of the preceding administrative remedies.

Question. I understand that failure to pay refunds is one of the major issues involved in a dispute over a letter of credit that the Department had negotiated with Phillips Colleges Inc., the nation's largest proprietary school chain, to cover such potential liabilities as unpaid refunds. The Department drew down about \$2.2 million of a \$5.5 million letter of credit last year to pay refunds, and Phillips has been slow to replenish the letter of credit. Are you following the Department's efforts to ensure that Phillips Colleges complies with refund requirements?

Answer. The Department did draw down \$2.2 million in August 1993 from the \$5.5 million letter of credit posted by Phillips Colleges, Inc. The basis of the draw down was unpaid refunds. Phillips was also slow in replenishing the letter of credit because it challenged the Department's authority to draw on the letter of credit. When Phillips lost its judicial appeals, it did replenish the \$2.2 million in February 1994.

My office identified Phillips failure to pay refunds in an audit report issued in July 1992. As part of the audit resolution process the Department has expended extensive resources to monitor Phillips refund activities. This monitoring resulted in the establishment of the \$2.2 million liability. We have also been kept apprised by the Department of their actions regarding the refund and other deficiencies involving Phillips.

Question. Since Phillips is a chain with 40 schools and 16,000 students, a substantial amount of Title IV funds could be at risk. Do you have any estimates of the potential liabilities in this case?

Answer. We cannot estimate the potential liabilities of Phillips. However, the Department does have several controls in place to reduce the risk of liabilities. As part of the financial responsibility settlement agreement, Phillips is under an escrow agreement where 50 percent of the loan funds are held by an independent escrow agent until they are earned by Phillips. This reduces the potential loan refund liability. Also, all of the Pell Grant funds are delivered on a reimbursement basis rather than the normal advance funding basis.

Question. All of the examples of refund fraud cited in your prepared testimony involve for-profit, proprietary schools. Do you receive many complaints of failure to pay refunds from other types of schools, such as community colleges and nonprofit institutions?

Answer. It is fair to say that the preponderance of complaints received by the OIG dealing with the failure to make refunds come from former students of the vocational trade and technical schools. While we may occasionally receive complaints from students of the other types of Postsecondary institutions you mention, they are much less in number.

Question. Does the Department agree with the GAO recommendation in a March 1993 report to amend the Higher Education Act to require that originating lenders pay loan origination fees even if the loan is subsequently sold to another lender or secondary market? To what extent would this provision alleviate the problem of nonpayment of origination fees?

Answer. Responding to the GAO Report, the Department concurred with this recommendation stating that it believes the act should also be amended to require guarantee agencies to collect origination fees from lenders and forward the fees to the Department when they submit their monthly billings.

Our office is in agreement with GAO that implementation of this change will strengthen the Department's ability to monitor and collect origination fees owed by lenders. To the extent that the problem is caused by an inability to determine when loans are sold and what party is responsible for paying related fees, this change should correct the problem.

Question. Lenders sometime sell guaranteed student loans before paying the related origination fee and the Department's regulations provide that either the seller or the buyer of a loan can pay the fee. Does the Department have any estimates of the amount of money lost as a result of nonpayment of origination fees?

Answer. As I mentioned in my May 13, 1994 testimony, the Department does not have an adequate internal control system to track submission of Forms 799, the form lenders are required to submit quarterly showing the amount of origination fees they owe the Department. Absent these internal controls, ED is unable to determine the amount of origination fees outstanding.

Question. You have stated that the Department of Education does not know who is originating loans unless the lenders report it. It seems to me, however, that the guarantee agencies must have a record of every loan originated. Is it possible for the Department to obtain this information from the guarantee agencies?

Answer. Your assumption is correct. The guarantee agencies do have a record of every loan originated. Also, the Department can, and does obtain this information from the guarantee agencies. However, the collection of the information is not timely and there are problems with its accuracy. This information is contained in what is known as the guarantee agency tape dump. By the time the Department has the tape dump in a useful format, it is usually between one and one-half to two years old. During this period a lender can be originating loans without the Department's knowledge if the lender does not submit Form 799.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

STATEMENT OF MICHAEL MANGANO, DEPUTY INSPECTOR GENERAL

Senator HARKIN. Our last subject matter concerns the supplemental security income program. We have Deputy Inspector General Mangano and Social Security Commissioner Shirley Chater.

Your written statements will be inserted in the hearing record. I understand that Inspector General June Brown is a little under the weather today. We are glad to have you back, Mr. Mangano, again this year.

The detailed statements will be inserted in the record. I would ask you to summarize your remarks, and we will withhold questions until we have heard both of you.

I guess my instructions are to begin first with Mr. Mangano of the Inspector General's Office.

SUPPLEMENTAL SECURITY INCOME PAYMENTS TO DRUG ADDICTS AND ALCOHOLICS

Mr. MANGANO. Thank you very much, Mr. Chairman. I am pleased to be here with you this morning to share the observations, findings, and recommendations from our ongoing studies of the supplemental security income payments to drug addicts and alcoholics, termed DA&A's, disabled children, and non-English speaking disabled individuals who use interpreters acting as middle-men to obtain eligibility.

My oral testimony will focus on the DA&A issue. All three topics are critically important and can only be fully and properly addressed by public discussions leading to congressional decisions.

We want to be assured that the program that has emerged is meeting the intent of the Congress when it established it, particularly with the DA&A's and the children.

The SSI program requires that the substance addicted recipients be in treatment, have the treatment monitored, and receive payments through a representative payee. While these requirements should lead to rehabilitation and reduced dependence on SSI, we found that few recipients leave the rolls because of successful treatment.

In 1991, we completed our first study focused on DA&A issues. While SSA paid \$55 million to almost 20,000 DA&A recipients in 1990, the Agency was mostly unaware of the treatment status provided and the little monitoring could identify only 8 percent as being in treatment.

Referral and monitoring agencies established by SSA to get addicts into treatment and to monitor their participation existed in only 15 States. Inconsistent interpretations of the provisions had

caused an uneven population distribution across States, and wide variations in treatment approaches.

To address our recommendations, Social Security has initiated various corrective actions which should lead to clear diagnostic criteria for addiction disorders, and more effective referral and monitoring agencies in every State by the end of the fiscal year.

Meanwhile, the DA&A population has increased from about 20,000 in 1990 to over 80,000 today. Some of the possible reasons for that include better identification by the Social Security Administration, a 1990 U.S. court of appeals ruling, the *Wilkerson v. Sullivan*, that substance abuse addiction can be disabling in the absence of other impairments, State referral of general assistance recipients, word on the street about SSI payments and SSI outreach to the homeless.

Whatever the reason for this rapid growth, it is clear that very few DA&A recipients are leaving the rolls. A recent analysis of about 200 recipients from our earlier review shows that after more than 3 years, 76 percent continued to receive SSI. Of the rest, one-half had died, and only one had left the rolls because of the ability to work.

We recently expanded our analysis to look at the entire DA&A population as identified in the Social Security records. We found that almost one-half live in two States, California and Illinois, and remarkably only 38 individuals in the District of Columbia are shown as receiving SSI because of drug or alcohol addiction.

One-fifth of the drug addicts and alcoholics receiving SSI also receive Social Security benefits. Paradoxically, nearly one-half of these concurrently entitled individuals receive Social Security disability payments directly from SSA while receiving SSI payments through a representative payee.

The general characteristics of the DA&A population, of whom 40 percent are adults under age 40 and over 70 percent are male, suggest that absent their addiction they would be employable. Yet it appears that these recipients are more likely to die than to turn to productive employment.

It is not clear from the available data whether this is the result of a flawed program design or flawed implementation, or whether participating in treatment is unlikely to result in rehabilitation.

In practice, approaching substance addiction as an entitlement issue seems to have subordinated treatment efforts to the demands of adjudication and paying claims. Moreover, the policy of tying payment to treatment appears to provide a strong disincentive to rehabilitation.

Recipients who successfully complete a treatment program, as well as those who fail to comply with the treatment requirements, can expect the same outcome—their SSI payments will stop.

Even those who succeed at rehabilitation face the task of finding employment difficult for this population, having little or no work experience, and over one-half of whom are over age 40.

I want to reiterate my belief that public discussion is needed to ensure that this program is consistent with congressional intent. Meanwhile, we are continuing to review several areas, including the effectiveness of the referral and monitoring agencies, the extent to which payees and recipients understand the treatment require-

ments, and the characteristics and availability of treatment programs.

PREPARED STATEMENT

The DA&A program is but one example of current problems in the SSI program. More details about this and the other vulnerabilities related to childhood disability issues and interpreter fraud appear in my written testimony.

I will be happy to answer any questions you may have.
[The statement follows:]

STATEMENT OF JUNE GIBBS BROWN

Good morning Mr. Chairman and members of the committee, I am June Gibbs Brown, Inspector General of the Department of Health and Human Services. I am pleased to be here to share with you the observations, findings, and recommendations from our ongoing studies of Supplemental Security Income [SSI] payments to drug addicts and alcoholics [DA&A's], disabled children and non-English speaking disabled individuals who use interpreters acting as middlemen to obtain eligibility.

I believe these are critically important issues that can only be fully and properly addressed by public discussion leading to congressional decisions. We want to be assured that the program that has emerged is meeting the intent the Congress had in establishing it—particularly for the DA&A's and children. I commend you for holding this hearing.

Let me begin, if I may, by reviewing the origins of SSI payments to drug addicts and alcoholics. I will use the acronym "DA&A" to refer to this eligibility category.

DRUG ADDICTS AND ALCOHOLICS

Background

In 1972, there was considerable debate about including drug addict and alcoholic provisions in the original SSI legislation. Initially the Senate sought to exclude these individuals from the Supplemental Security Income program by establishing a special, separate program. The Senate was sensitive to the fact that these DA&A's needed more than the income maintenance that SSA could provide, envisioning a need for treatment and case management as well as assistance in cash management so that government payments would not be used to feed their addiction.

The treatment requirement was clearly intended to be rehabilitative with the Senate seeking "rehabilitative services under a program of active treatment." The House characterized it as "appropriate treatment at government expense using Secretarially approved providers * * * an essential part of the rehabilitative process of people so disabled."

Congress ultimately passed legislation (Public Law 92-603) that combines the income maintenance payments and treatment as part of the Supplemental Security Income program but required that such payments be made through a representative payee. Congress specifically required that DA&A's undergo appropriate treatment where treatment is available, and have their participation in this treatment monitored.

These unique requirements apply to no other category of disabled individuals. Clearly, drug addicts and alcoholics are expected to assume some responsibility for overcoming their self-inflicted disability in order to become productive members of society. Though this would ideally lead to a reduced dependence on Supplemental Security Income payments, our experience thus far indicates that this expectation is rarely being realized.

Office of Inspector General studies

We initially became involved in the DA&A issue during a 1990 review of the availability of representative payees. Though not specifically focused on the DA&A population, we found that these recipients challenged SSA's ability to find suitable representative payees. We also identified data discrepancies that raised questions as to whether individuals disabled on the basis of drug addiction and alcoholism were being properly identified as such in SSA records. Since only those clearly identified as drug addicts and alcoholics are subject to the requirements for representative payment, treatment, and monitoring, it was not clear if these requirements

were being fully implemented. Based on these initial incongruities, we felt obligated to further investigate the implementation and effectiveness of the DA&A provisions.

In July 1991, we completed our study of Social Security policies concerning drug addicts and alcoholics. This review specifically focused on assessing the Social Security Administration's implementation of the unique eligibility requirements for recipients eligible on the basis of substance abuse.

Management of the Drug Addict and Alcoholic Program

Although in 1990 SSA was spending \$55 million annually in SSI payments to DA&A recipients, it did not know whether these recipients were meeting the requirements of the program. While these recipients had the required representative payees, SSA was mostly unaware of their treatment status and provided very little monitoring. At that time, SSA could only identify 8 percent of 19,760 recipients as being in treatment.

To implement the treatment monitoring provisions of the law, SSA established Referral and Monitoring Agencies. Although these agencies were specifically responsible for referring the drug addicts and alcoholics to available treatment programs and monitoring their participation in treatment, they only existed in 15 States. Moreover, there were wide variations in approaches these agencies used, ranging from a full program of case management and vocational counseling to contacting treatment programs by mail to track attendance. Little referral and monitoring was done in States without specific Referral and Monitoring Agencies.

We also noted that unclear SSA guidelines resulted in inconsistent interpretation of the DA&A provisions. There were widespread differences in the numbers of drug addicts and alcoholics found eligible from State to State. A significantly higher proportion of these recipients than those in the general SSI population became eligible after appealing initial denials (40 percent compared to 16.7 percent). We also found that since treatment was not clearly defined, wide variations in approaches were accepted as meeting the treatment requirements, including detoxification, outpatient therapy, and maintenance programs such as Alcoholics Anonymous.

We recommended that SSA work with the Public Health Service and the Health Care Financing Administration to develop clearer definitions for drug addicts and alcoholic status, treatment, and successful rehabilitation. To facilitate improved management of this program, we suggested that SSA correct the Supplemental Security Record to reflect the current status and treatment of these recipients. Finally, we advised that SSA strengthen the referral and monitoring system to ensure that recipients receive and participate in available treatment and that appropriate eligibility decisions can be made when individuals either fail to comply with the requirements or successfully complete their rehabilitation.

Program enhancements underway

With the exception of the noted data deficiencies, SSA agreed with our findings and initiated actions to address these concerns. After extensive consultation with the Public Health Service, the States and appropriate medical experts, SSA developed clearer diagnostic criteria for addiction disorders.

In collaboration with the Public Health Service's Substance Abuse and Mental Health Services Administration (SAMHSA), they have developed a model protocol which is intended to establish a comprehensive, uniform, and cost-effective process for referral and monitoring. Under this protocol, contractors are required to perform specific tasks that should lead to greater management oversight of the referral and monitoring process and hopefully better treatment services for the drug addicts and alcoholics. SSA has contracts in place in 34 States and plans to negotiate contracts in the remaining States by the end of this fiscal year.

In addition, SSA is working with SAMHSA on two joint demonstration projects to test alternative treatment and rehabilitation services. These actions would seem to address many of the concerns from our earlier inspection.

Growth in the drug addict and alcoholic population

The DA&A population has increased from as many as 24,000 in 1990 to more than 80,000 today. A number of factors have been suggested as contributing to the growth.

First, it is possible that SSA's actions taken as a result of our earlier work and their response to a U.S. Court of Appeals decision (*Wilkerson v. Sullivan*), also in 1991, may have influenced State Disability Determination Services to identify disabled recipients as substance abusers more accurately. After the *Wilkerson* decision, SSA issued guidelines to the State agencies clarifying the definition of disability when applied to DA&A cases.

In addition, there are indications that individual States are increasingly encouraging adult general assistance recipients, many of whom are substance abusers, to

apply for SSI. In some instances States have established special units to assist these people in developing needed information to facilitate the SSI application and appeal processes. There was also the spreading of the "word on the street" that SSI payments are an attractive source of income. The SSA has also pointed to their own efforts at SSI outreach, particularly among the homeless, as raising awareness among the drug addict and alcoholic population of their potential eligibility for SSI payments.

Minimal positive outcomes from current treatment requirements

Whatever the reason for the growth in the number of drug addicts and alcoholics coming onto the SSI rolls, it is abundantly clear that very few are leaving the rolls. Based on our recent analysis of a sample of 197 drug addicts and alcoholic recipients who had been included in our 1991 review, we found that, after more than 3 years, most drug addicts and alcoholics continue to receive SSI.

For the 24 percent that stopped receiving SSI, half had died; 20 percent became ineligible because of the amount of their other unearned income, typically Social Security benefits; and 10 percent were imprisoned. Only one of 197 recipients in our sample left the SSI rolls due to significant earnings or medical improvement. Despite treatment requirements, drug addicts and alcoholics continue to rely on SSI. We do not know if this is because treatment is not effective, participation is not genuine or not tried, or what. All we know is that the combined set of program requirements for SSI DA&A recipients is not leading to rehabilitation.

Demographics of DA&A population

As part of our continuing analysis, we are also looking at the demographics of the DA&A population. As we reported in 1990, there continues to be an uneven distribution of these recipients across the nation. Almost half of the substance abusing recipients live in two States, California and Illinois. Conversely, according to SSA's coding, there are only 38 individuals in the District of Columbia receiving SSI payments based on drug or alcohol addiction.

The types of payees for DA&A's vary widely. While more than half of payees are relatives, one-third are non-relatives, including friends, acquaintances, and professionals such as attorneys. In contrast only one-tenth of all SSI disabled adults (ages 18 to 64) have payees that are in this "other" category. More importantly, one-fifth (16,810) of drug addicts and alcoholics are concurrently entitled, that is receiving both Social Security disability and SSI payments. Nearly one-half (7,460) of these recipients receive their Social Security benefit directly, quite often receiving equal or greater benefits directly under the Social Security program while the SSI payments must be made through a representative payee. It certainly seems incongruous that the Government would require a representative payee to manage SSI payments but not other payments based on drug or alcohol addiction distributed by the same agency. It is our understanding that a legislative action would be needed to extend the payee requirement to title II benefits.

In looking at their general characteristics, we find that more than 40 percent of the drug addicts and alcoholics are young adults, aged 18-39, and more than 70 percent are male. These characteristics would suggest that, absent their addiction, they should be employable. Our experience over the past few years shows that these individuals are more likely to die or go to jail than to turn to productive employment. As indicated above, it is not clear whether this is the result of a flawed program decision, flawed implementation, or whether participation in treatment is unlikely to result in rehabilitation.

Disincentives to rehabilitation

The policy of tying payments to treatment, even though it has not been fully implemented, would seem to establish a very strong disincentive for recipients to succeed at rehabilitation. Even those who do succeed at DA&A rehabilitation may then face a difficult task of finding employment. This is particularly difficult for this population because they have little or no work experience and more than half are over age 40.

First, these individuals go through an often lengthy and difficult process involving perhaps several levels of appeal, to establish eligibility to SSI payments. Once their eligibility is established, they are advised that they must be in a treatment program, if one is available, in order to maintain eligibility. While this process seems logical, individuals who fail to comply with the treatment requirements and those who successfully complete their treatment can expect, if the process works as designed, the same outcome. Their SSI payments would stop.

Issues requiring further study

One major issue concerns the effectiveness of Referral and Monitoring agencies in ensuring that individuals are enrolled in treatment programs. Equally important is whether the payees and recipients understand treatment requirements, whether treatment is available when needed, and whether it is having the intended outcome. Similarly, it is not yet clear what treatment approach is appropriate for those individuals who are unlikely to overcome their addiction and return to productive employment. Other issues include payment management, and the relationship of addictions to other disabling conditions.

To address some of these issues, we are conducting the following reviews:

—*SSI Drug Payments to Drug Addicts and Alcoholics: Continued Dependence.*—

This review will update and expand on information about drug addicts and alcoholics reported by the Office of Inspector General in March 1994. Because of the small size of the sample used for that report, we are in the process of comparing the entire DA&A population from our earlier study (June 1990) and the DA&A population as of February 1994 to determine their status. This review will also provide an update on the status of data deficiencies in SSA records detected during an earlier review.

—*Effectiveness of DA&A Requirements for SSI Recipients.*—This review has two purposes. The first is to describe the nature of the relationship between SSI recipients disabled due to drug addiction or alcoholism and their representative payees, particularly as it relates to the management of benefits. The second is to describe the nature and extent of these recipients' participation in treatment programs.

These reports should be available in August 1994. We will be happy to share them with your subcommittee.

PAYMENTS MADE ON BEHALF OF CHILDREN

The second program area I would like to discuss in my testimony is SSI disability payments to children. The number of disabled children enrolled in SSI rose from about 296,000 in 1989, to over 761,000 in 1993, an increase of 257 percent. The cost of the SSI program for children rose from about \$1.2 billion in 1989 to about \$4.5 billion in 1993. The primary cause of this increase was a 1990 U.S. Supreme Court decision, *Sullivan v. Zebley*, which required SSA to change its method of evaluating childhood disability. Part of the increase in the number of eligible children may also be due to expanded outreach which the Congress has required since 1990.

Several members of Congress have expressed concerns about the provisions of this eligibility category. We have met with your staff, with the staff of Senator Herb Kohl and others to bring some focus to the problems perceived in evaluating childhood disability. As a result, we are reviewing the adequacy of guidelines provided by SSA to the States' Disability Determination Services [DDS] which are responsible for determining the medical eligibility of SSI applicants. We are reviewing DDS compliance with these guidelines in 10 States; and, at the request of your staff, we have also begun a nationwide review to determine if SSI payments were inappropriately denied to children who are genuinely impaired.

Legislative history

During the legislative process to establish the SSI program in 1972, there was a difference of opinion between the House of Representatives and the Senate concerning the participation of persons under the age of 18. The House justified its inclusion of disabled children in SSI on the grounds that " * * * the needs of disabled children are often greater than those of nondisabled children * * *."

The Senate disagreed, stating that " * * * the needs of disabled children are generally greater only in the area of health care expenses * * *." According to the Senate, children receiving cash assistance are covered under existing State medical assistance programs and are, therefore, having their health care needs addressed by these programs. The Senate also concluded that " * * * disabled children's needs for food, clothing, and shelter are usually no greater than the needs of nondisabled children." The Act was subsequently passed and children were included in the SSI program.

In implementing the Act, SSA established different methods for determining eligibility for adults and for children. Adult eligibility was determined on the basis of a medical listing of impairments and, if necessary, a functional assessment of an adult's capacity to work. On the premise that children could not be expected to have a capacity to work, child eligibility was determined solely on the basis of a medical listing of impairments.

The Sullivan v. Zebley Supreme Court decision

The difference in the eligibility determination process for adults and children, namely the lack of a functional assessment for children, became the focus of the *Sullivan v. Zebley* Supreme Court decision of February 20, 1990.

In a 7 to 2 decision, the Supreme Court found that an " * * * inquiry into the impact of an impairment on the normal daily activities of a child of the claimant's age—speaking, walking, washing, dressing, and feeding oneself, going to school, playing, etc.—was no more amorphous or unmanageable than an inquiry into the impact of an adult's impairment on his ability to perform substantial gainful work * * *." The Supreme Court thus held that the Department's approach to child disability was "manifestly contrary to the statute."

Effect of "Zebley" on the SSI Program

In response to the Supreme Court's decision, SSA, in 1991, issued proposed regulations stating that if a child's impairment is not on the listing of physical or mental impairments, SSA must determine if the impairment " * * * so limits the child's ability to function in an age-appropriate manner that the limitations are comparable in severity to those that would disable an adult." The regulations were finalized in September 1993. To make this determination, SSA makes a functional assessment of a child's cognitive skills, communication skills, motor skills, social skills, personal behavior and concentration persistence pace. We noted that the eligibility of 31 percent of the 269,309 children enrolled in the SSI program in Calendar Year 1992 was based on a functional assessment.

Preliminary results of our audit

It appears as though Congress included disabled children in the SSI program on the assumption that they often have greater financial needs than nondisabled children. There was no discussion in the legislative history as to what these financial needs are or how SSI payments are to meet them.

Preliminary results in a number of States, for those categories of mental disability included in our review, show that a substantial number of children were also enrolled in the Aid to Families With Dependent Children [AFDC] and Medicaid programs. Also, school age children were receiving special education services at the time that they applied for SSI benefits. If these results are confirmed in the rest of our study, the Congress may wish to consider the particular focus and purpose of SSI payments to children and whether the current program is designed to meet those ends.

We expect to issue a profile report on the children included in our 10-State review. This report will provide information on the financial, medical and educational services available to these children at the time they applied for SSI benefits. The report will also describe, in some detail, the Medicaid services received by these children both prior to and after SSI enrollment.

SSA guidelines and DDS compliance

Based on our work to date of calendar year 1992 SSI approvals, we believe that there is a need for SSA to clarify its instructions to the DDS's for measuring the severity of a child's impairment, particularly with regard to children determined eligible on the basis of a functional assessment. Because the functional assessment criteria are, in our opinion, vague and subjective, we have identified some children whose disability and subsequent eligibility is questionable. These cases are being forwarded to SSA for review.

We noted that SSA became aware of the need to clarify its instructions through a recent special review of about 600 SSI cases. As a result of this review, SSA has issued numerous bulletins to the DDS aimed at clarifying issues that arose during SSA's review. We are currently obtaining the views of DDS personnel on the adequacy of SSA's guidance.

Next step

We are now reviewing a nationwide, random sample of children with mental disabilities who were denied benefits during calendar year 1992. We will determine whether these children were inappropriately denied benefits. We will also determine whether they were enrolled in the AFDC, Medicaid and special education programs at the time of their SSI applications.

SSI INTERPRETER FRAUD

The third program area I would like to discuss pertains to the use of interpreter middlemen by some non-English speaking applicants to obtain SSI eligibility. SSA has identified a large number of cases, particularly in Southern California, in which

interpreters hired by the applicants may have misrepresented the individuals' physical or mental condition to get benefits.

Investigative background

While interpreter fraud schemes are not a new phenomenon in administering Federal programs, this type of fraud surfaced as a serious problem in the SSI program in the late 1980's. The first case of interpreter fraud to receive widespread publicity was in Southern California and involved interpreters who represented Southeast Asian refugees. While the problem does not appear to be as pervasive in other parts of the country, we have received allegations of possible fraud in a number of other areas involving a variety of non-English speaking groups. In response, our office has opened investigations throughout the country.

We have identified some similarities in these cases: most of the disability claims involve mental impairments; many claimants of the same non-English speaking group use the same interpreter and, often, the same treating source, providing repetitious allegations and verbatim medical evidence; and in interviews it appears that interpreters typically respond to questions either without claimant input or based on an obviously rehearsed script.

Because of the language barrier, the interpreter provides all verbal communication with the doctor and with SSA interviewers. Thus, there is no opportunity to detect indications that the subject is not telling the truth.

OIG activity

The SSA began referring interpreter fraud allegations to our office in the late 1980's. Investigations began in 1987. Subsequently, two subjects pleaded guilty in 1989 for conspiracy and for aiding and abetting in a scheme to defraud the SSI program. In early 1991, allegations began to surface of widespread fraud in the SSI disability and Medicaid programs in the Los Angeles area. Our office in Los Angeles began investigating these allegations in October, 1991 because of a request for assistance from the California Attorney General's Bureau of Medi-Cal Fraud and Patient Abuse.

By May, 1993, our office had 10 agents involved in conducting HHS fraud investigations in Southern California. We conducted undercover activities and obtained operatives to pose as SSI applicants and approach interpreters to act as middlemen. To date, the undercover operations have resulted in approximately 30 search warrants and 18 arrests.

We have found indications of interpreter fraud in several regions of the country other than California. For example, a 1991 case involving a Russian interpreter in Brooklyn resulted in a conviction for conspiracy and false statements. The interpreter and her spouse were convicted. The spouse was incarcerated.

In the last two years, our office has stepped up its interpreter fraud investigation efforts nationwide. As of February 4, 1994, 10 search warrants were issued in Tacoma Washington. To date, 9 individuals have been arrested and charged in connection with this large-scale scheme to fraudulently qualify refugees for SSI. Four of the 9 individuals arrested were SSI recipients. Of the 9 who were arrested, 2 interpreters, 1 caseworker and 1 beneficiary have pled guilty. Other individuals are targeted in this investigation.

We recently initiated an audit on the use of interpreters in applying for SSI. The primary objective of our review will be to evaluate the procedures used by the Social Security Administration [SSA] when processing SSI disability claims filed by non-English speaking individuals. Specifically, our auditors will determine whether SSA's current procedures are adequate to both detect and prevent fraudulent or abusive claims. In addition, the auditors will assist our investigators in their continuing efforts to gather sufficient evidence to pursue criminal prosecutions.

Our auditors are also working with SSA on a regional project in California. The primary objective of the project is to remove non-disabled individuals from SSI payment status. This project will determine what data bases and controls can be established to monitor interpreters and/or physicians who assist non-English speaking applicants. The project will explore the feasibility and cost of contracting interpreter services from private telecommunications, rather than hiring multilingual employees from the same communities as the interpreters, who could subject the employee to harassment or threats.

Limitations on criminal remedies

We face several limitations in documenting interpreter cases for prosecution. We are usually dealing with tight-knit ethnic communities. It is difficult to obtain witnesses and difficult to get undercover people inside the operation.

Under the current methods of evaluating mental impairments, allowance decisions are often based on a finding that the applicant meets a medical listing or has

limited residual functional capacity. Applicants often allege having no prior medical evidence and the DDS must rely on brief consultative examinations to make their decisions. Communication and cultural differences, plus the life experiences of many applicants (especially refugees), make it difficult to prove a mental disability is not present.

Where only outside interpreters are involved, it is difficult to show intent to defraud; and, if so, whether the intent was on the part of the applicant, the interpreter, or both. When the interpreter fraud scenario includes dishonest medical professionals who conspire with the interpreter and the applicant to submit false records, it is a challenge to obtain reliable counter evidence without Government-approved interpreters.

If the applicant has been well coached by the interpreter and/or a medical professional, even the presence of an approved interpreter may be inadequate to deter fraud.

Prevention

While we will continue to actively investigate these types of cases, we maintain that the best overall solution to the problem is prevention. Our office submitted a report to SSA in April 1990 on serving non-English speaking clients. SSA generally agreed with our recommendations and is implementing several improvements in its service delivery.

We issued two OIG Fraud Alerts on interpreter fraud schemes to SSA field offices. Fraud alerts are short descriptions of reported schemes which could occur in multiple locations. The two fraud alerts were distributed to all SSA and OIG field offices. The fraud alerts were disseminated to SSA claims representatives who, because they are in a position to identify patterns of similar cases, are one of our best sources of detecting suspicious cases.

We are also exploring, with SSA, the use of the Program Fraud Civil Remedies Act against persons involved in schemes to defraud the SSI disability program. We believe that current statutory authority for imposing civil penalties for false claims and statements under 31 U.S.C. 3801-3812 and our implementing regulations, 45 CFR Part 79, are broad enough to permit imposition of penalties in interpreter fraud cases. As we continue to conduct these investigations, we will be reviewing cases to determine where imposition of such penalties would be appropriate.

We have met with SSA to discuss whether SSA should seek other sanction authorities or a more streamlined sanction process since imposition of penalties under PFCRA is time-consuming. We have agreed to work with SSA to develop a legislative proposal. We will, of course defer to SSA as to the specifics of any additional authorities they may seek.

The Department of Justice may also seek civil monetary penalties in Federal court under the Civil False Claims Act, 31 U.S.C. 3729-3733. We will, of course, refer any case to the Department of Justice where the imposition of such penalties might be appropriate. Additionally, under 31 U.S.C. 3803(a)(3), all proposed program fraud civil remedies must be submitted to the Attorney General for review.

We believe progress is being made to identify and control the spread of interpreter fraud; and, again, I stress that the best broad-based solution is prevention through good service and communication.

Mr. Chairman, we appreciate your interest and support in examining these important program issues. Supplemental Security Income has grown substantially in recent years, and it is highly appropriate that these problems be scrutinized and corrected. Much of what we are seeing in SSI today requires a revisiting of congressional intent regarding the goals and outcomes of the program. Thank you for including us in this important dialogue. I will be happy to answer any questions you may have.

Senator HARKIN. Thank you, Mr. Mangano. We do have some questions, but first we will hear from the next witness.



SOCIAL SECURITY ADMINISTRATION

STATEMENT OF SHIRLEY S. CHATER, Ph.D., COMMISSIONER OF SOCIAL SECURITY

Senator HARKIN. We will now move to Dr. Chater, the Commissioner for the Social Security Administration.

Welcome to the subcommittee, and if you could please summarize your statement we would appreciate it.

SUMMARY STATEMENT

Dr. CHATER. Mr. Chairman, I too appreciate this opportunity to join you today to discuss our mutual desire to protect the Supplemental Security Income Program from fraud and abuse.

I am pleased to bring you up to date on some recent actions taken by the Social Security Administration to achieve this objective. In the interest of brevity, my written testimony discusses in detail the issues you have requested the agency to address—childhood disability, interpreter fraud, and our actions concerning SSI recipients who are substance abusers.

I would like to spend my time this morning discussing the last of these three topics, SSA's efforts to work with SSI recipients who are disabled by drug addiction and alcoholism.

The two specific questions you have asked, Mr. Chairman, I would like to address. The first one concerns the significant increase between 1990 and 1993 in the number of SSI recipients who are identified as substance abusers.

The other concerns the initiatives we are taking to improve the system by which these recipients are referred for treatment and subsequently monitored.

You are correct in stating that the number of SSI recipients designated as drug addicts or alcoholics has grown dramatically. In fiscal year 1990, they constituted 1 percent of the total SSI disabled population, but by the end of fiscal year 1993, that proportion had grown to 2.6 percent or about 79,000 people.

We think there are two predominant reasons for this increase. The first one is the active outreach effort that SSA has undertaken in recent years, with the support and encouragement of Congress. The outreach program is focused on certain segments of the population who may be eligible for SSI benefits, including, for example, the homeless, many of whom have substance abuse problems.

The second reason for the increase is that SSA is doing a better job of correctly identifying recipients who have substance abuse problems. We have strongly emphasized to the State Disability Determination Services the importance of accurately identifying cases involving drug or alcohol related impairments.

In fact, the Social Security Administration issued an extensive program directive on this issue to the States in April 1991, which

is about the same time that the number of SSI substance abuse cases began to significantly increase.

So, in summary, we believe that the recent growth in the number of individuals receiving benefits based on drug addiction and alcoholism can be attributed to more effective outreach and also better identification of recipients.

Now, I would like to turn to the issue of treatment referral and monitoring of recipients. Until recently, SSA has attempted to ensure compliance with the treatment and monitoring requirements in the law through agreements with States and private contractors who serve as referral and monitoring agencies, [RMA's].

This approach, frankly, has not worked very well. As of October 1993, we had RMA's in only 18 States, and only 45 percent of the SSI recipients identified as having a substance abuse problem were being monitored. Also, SSA did not provide specific guidance to the referral and monitoring agencies about how they should function on a day-to-day basis.

We have taken major steps to improve this process, and today each referral and monitoring contractor is required to perform numerous specified tasks that will ensure both better service to SSI recipients and greater management oversight by SSA.

These requirements include, but are not limited to, monitoring of the treatment compliance of recipients on an ongoing basis, weekly for some periods, for example. It also involves adherence to detailed procedures for dealing with instances of treatment refusal and non-compliance.

It also involves assessment of each recipient no later than the 24th month of treatment, and, if appropriate, referral at that time for vocational rehabilitation.

These new contracts are currently in place in 34 States and the District of Columbia, and we anticipate contracts with the remaining States by the end of this fiscal year.

Mr. Chairman, funding for these referral and monitoring activities increased from \$4 million in fiscal year 1993 to \$20 million in fiscal year 1994, and we have requested \$36 million in funding for fiscal year 1995. This additional funding would allow us to serve about 69,000 SSI recipients disabled by drug addiction and alcoholism in fiscal year 1995, close to twice the number we will serve this fiscal year.

Since we proposed the fiscal year 1995 estimate, however, our recently revised projections indicate that more persons will need referral and monitoring. We are evaluating this information and will come back to the committee once that evaluation is completed.

There are also other initiatives that we are taking and testing in this area. Included among them are efforts to encourage non-profit organizations to provide representative payees to handle the SSI benefits received by individuals disabled by drug addiction and alcoholism.

We are participating in demonstration projects to explore the possibility of sending SSI payments directly to the treatment provider or the referral and monitoring agency. This is discussed in my written statement in greater detail.

I would also like to add that the version of my written statement that was submitted in advance to the committee expresses support

for specific deficit-neutral provisions of the legislative measures that were passed by the Senate and favorably reported by the House Ways and Means Committee.

While we support the goals and the general direction of these legislative remedies, we are still reviewing the potential impact of several of the specific provisions within the legislation, and wish to withhold final recommendations until that review is completed.

As I indicated earlier in my statement, my written statement does address this committee's concern about interpreter fraud and also childhood disability.

I will simply say that we have launched a number of initiatives to prevent interpreter fraud, including improving and expanding services to non-English speaking claimants and beneficiaries.

On the subject of childhood disability, we have recently completed a 600-case study of childhood disability claims to determine if the new 1990 regulations have been applied correctly, if there was any evidence of parental coaching of child applicants, and if coaching affected the accuracy of decisions.

The study findings showed no evidence of widespread coaching or that coaching had influenced decisions.

On each of the issues discussed in my testimony, SSA is working closely with the Office of the Inspector General at the Department of Health and Human Services to effectively address the fraud and abuse problems that threaten the integrity of the SSI program.

I do thank you again for your interest in these issues, and I look forward to working with Congress and with all interested parties to consider other approaches that will help us to provide effective oversight of the SSI program.

We want to treat all beneficiaries with compassion, but we also need to ensure that the program is well managed, and that those individuals disabled by drug addiction and alcoholism who are able to do so seek treatments to improve their condition.

Mr. Chairman, I would be pleased to answer your questions, but I would like to read for the record a statement that has to do with performance bonuses. Would you like me to do that now or later?

Senator HARKIN. Absolutely. Please proceed, but could you pull the mike in a little bit closer. Just aim it right at your mouth. Go right ahead.

Dr. CHATER. Let me briefly mention a few words regarding cash performance bonuses at SSA. I am very deeply concerned about the misunderstandings and the resulting negative publicity that has surrounded this issue over the past 2 weeks.

The real losers have been not only SSA's 64,000 highly productive employees, but all Federal employees. And unfortunately, most critics have focused on one particular cash bonus paid to a man who has dedicated his entire career to public service, my principal deputy, Dr. Lawrence Thompson.

SSA's payment of performance bonuses is not unique to the Federal Government. The dollars we paid as a percentage of our payroll, 1.15 percent, is in line with other Federal agencies. And while SSA's work force declined 20 percent in the late 1980's, its workload increased over 70 percent, and it was only through greater productivity improvements of this talented work force that SSA has been able to continue providing quality service to the public.

Despite my strong support for rewarding highly competent Federal employees, the events over the past 2 weeks have led us all to take a closer look at our policies in this area. We do not want the focus of this important issue to continue to dwell on one particular award.

At the time of his award, Mr. Thompson had been serving as SSA's Acting Commissioner for about 3 months. The award was based also on his exemplary performance at GAO for 9 months preceding, and seemed an appropriate action at the time.

PREPARED STATEMENT

Dr. Thompson and I both understand the sensitivity and the concern that has been expressed regarding the fact that this bonus was paid by SSA. Consequently, based on this concern and the basic issues raised by many regarding its fairness, and consistent with regulations that govern such award, not to mention how it might adversely impact the future payment of awards to dedicated Federal workers, Dr. Thompson has voluntarily decided to return the entire performance bonus.

Thank you very much for allowing me to read this for the record. [The statement follows:]

STATEMENT OF SHIRLEY S. CHATER

Mr. Chairman and members of the subcommittee, I am very pleased to be here today, especially since this is the first occasion I have had to appear before your Subcommittee. I appreciate your interest in the Supplemental Security Income [SSI] program and share your concerns about fraud and abuse.

As you know, the Social Security Administration [SSA] has important responsibilities and enormous workloads. For example, in fiscal year 1993, we paid federally administered (Federal and State) SSI payments to about 6 million persons. Moreover, in fiscal year 1995, SSA will provide benefits to 47 million people, issue 16 million Social Security cards, handle 230 million annual earnings reports provided by employers, process 7 million claims for benefits, and handle over 50 million phone calls to our toll free 800 number. I am proud to say that in most instances, SSA employees do exemplary work. We need to ensure that the public has confidence in the program and believes that it is managed well and is not fraught with abuse.

I can assure you that allegations of abuse are taken seriously and investigated, and we have undertaken numerous efforts over the past year to ferret out abuse and improve the administration of our programs. Nevertheless, the SSI issues which you have asked me to address in this hearing—benefits for drug addicts and alcoholics and allegations of fraud and abuse within the SSI program—are complex issues, and we have been working hard to improve administration in these areas.

Before I begin, however, I want to thank our colleagues in the Department of Health and Human Services' [HHS] Office of the Inspector General [OIG], who have provided us with a great deal of assistance and information in dealing with these SSI issues. They have conducted several studies, providing data and analyses highlighting problems associated with the current system. Their input has been instrumental in helping us to begin solving the problems associated with drug addiction and alcoholism [DA&A], fraud, and abuse.

As you requested, Mr. Chairman, my testimony will primarily focus on the SSI program's treatment referral and monitoring process for persons who are disabled by DA&A. Following that, I will explain what we are doing about your concerns with regard to two other issues within the SSI program—allegations of interpreter fraud and allegations that children are receiving benefits on the basis of inaccurate medical evaluations.

DRUG ADDICTS AND ALCOHOLICS

Let me now turn to the issue of DA&A within the SSI program. Over the years, it has become clear to the medical profession that substance addiction is a disease which can legitimately be the basis for a finding of disability. The Congress and the

Administration concur with this finding. However, the American public has a right to expect that those disabled by substance addictions will not simply continue on the SSI disability payment rolls without taking responsibility for themselves. Unlike many other disabled individuals, those suffering from substance abuse can, to varying degrees, influence their recovery by their own actions. The public has the right, therefore, to expect that they will seek recovery from their addiction and become self-supporting.

Eligibility requirements

The SSI eligibility requirements for DA&A are the same as for other disabling conditions. That is, an individual: Must have a medically determinable physical or mental impairment that has lasted or is expected to last for a continuous period of at least 12 months or to result in death; and must be unable to perform substantial gainful activity because of the impairment.

Drug addiction and alcoholism are considered medically determinable impairments, and just as with any other impairment, a finding of inability to work depends on the severity (that is, the functional limitations caused by the impairment) and the duration of the impairment.

In addition to the medical requirements, Congress included two special requirements in the law for SSI recipients who are disabled by DA&A. It required that: These individuals undergo appropriate treatment for their addiction at approved facilities when treatment is available, and demonstrate compliance with the terms and conditions of such treatment. Also, they must receive their SSI payments through a representative payee.

These two special requirements were intended to prevent individuals from receiving cash payments without participating in an available treatment program and to prevent them from using cash payments to purchase drugs or alcohol. These requirements do not currently apply to Social Security disability beneficiaries, nor do they apply to SSI recipients who are found to be disabled independently of their substance addictions. For example, those SSI recipients who have an addiction but who are also disabled by another impairment such as heart disease are not classified as drug addicts or alcoholics for purposes of applying these requirements.

Increase in SSI DA&A rolls

Very few SSI recipients were identified as disabled by DA&A during the first years of the program. In the 1990's, however, there has been dramatic growth in the number of disability entitlements based on substance addiction, which includes both alcohol and drugs. Those identified as DA&A constituted 1 percent of the total SSI disabled population in fiscal year 1991; by the end of 1993, they made up 2.6 percent of the total SSI disabled population. Attached to my statement are two tables showing some statistics about SSI recipients disabled by substance addiction.

In your letter of invitation to appear at this hearing, you asked me to explain the sudden increase in the number of SSI recipients identified as substance abusers. We attribute this to two major efforts SSA has undertaken in recent years. First, at the urging of Congress, we have been conducting an active SSI outreach effort in the past several years. The outreach program is particularly focused on certain populations including the homeless, many of whom have substance abuse problems. This effort has been effective and has resulted in a greater awareness of the availability of SSI benefits for those with substance addictions.

Second, we have reemphasized to the State Disability Determination Services [DDS's] the importance of accurately identifying cases involving DA&A impairments. In April 1991, we issued an extensive program directive which reiterated how existing policies for determining disability apply to the evaluation of substance addiction disorders. In the last several years, we also have issued periodic "reminder items" both nationally and regionally to emphasize the need to accurately identify these cases.

Referral and Monitoring Agencies [RMA's], which have been established in most States, determine if appropriate treatment is available, refer beneficiaries to treatment, monitor treatment plans, and report to SSA if a beneficiary is not in compliance with the treatment plan. Consequently, more individuals have been identified as DA&A by DDS's in States that have had active RMA's to which to refer these individuals. We suspect that this phenomenon explains the rapid growth of substance abuse cases in the Chicago region. The SSA regional office in Chicago has worked to ensure that every State in the region has a functional and active RMA, and we now find that Illinois and Michigan rank second and third in the nation in the number of SSI disability recipients identified as disabled by DA&A.

We believe that better identification of current SSI recipients as substance abusers and greater awareness of the program's existence have resulted in the recent growth in the DA&A rolls.

Referral and monitoring

Now let me turn to the issue of administering the special DA&A provision of the law concerning treatment referral and monitoring which you specifically asked me to address. SSA's role in administering this provision is not to determine what kind of treatment is appropriate, but rather to find qualified agencies which are capable of making that determination. Nevertheless, we have evaluated how SSA administered this provision in the past and realize that we need to make improvements.

Until recently, SSA has attempted to ensure compliance with the treatment and monitoring requirements through agreements with States and private contractors serving as RMA's. In past years, however, SSA found it difficult to establish agreements with RMA's covering all locations in a uniform manner because of small workloads in some States and resource requirements for covering the whole country. As of October 1993, we had RMA's in only 18 States and only 45 percent of the persons identified as receiving SSI based on DA&A were being monitored. In addition, we did not provide specific guidance to the RMA's as to how they should function on a day-to-day basis.

I am pleased to report, however, that based on our collaboration with the Public Health Service's Substance Abuse and Mental Health Services Administration [SAMHSA], we have taken major steps to improve referral and monitoring services. We have developed a contract process structured to require each RMA contractor to perform numerous specified tasks that will assure both better service to SSI recipients and greater management oversight by SSA of the referral and monitoring process. These new contracts, which are now in place in 34 States and the District of Columbia, contain provisions requiring RMA's to:

- Review SSA files and conduct face-to-face interviews with each SSI recipient disabled by DA&A;
- Notify the representative payee of the individual disabled by DA&A of all actions occurring in the RMA process;
- Monitor the treatment progress of each SSI recipient disabled by DA&A on an ongoing basis (weekly for some period);
- Administer detailed procedures for dealing with instances of treatment refusal and noncompliance;
- Adhere to specific requirements for referring recipients for treatment; and
- Assess each SSI recipient disabled by DA&A no later than the 24th month of treatment and, if appropriate, refer him or her for vocational rehabilitation.

SSA will now be able to monitor the RMA's to ensure compliance with the specific tasks they have agreed to perform. Further, we plan to have RMA contracts in place in the remaining States by the end of this fiscal year.

Finally, funding for these activities increased from \$4 million in fiscal year 1993 to \$20 million in fiscal year 1994. And we have requested \$36 million in funding for fiscal year 1995, an 80 percent increase over fiscal year 1994. We previously estimated that the additional funding would allow us to serve about 69,000 SSI recipients disabled by DA&A in fiscal year 1995, close to twice the 39,500 recipients we expect to serve this fiscal year. Since we prepared the 1995 estimate, however, recently revised projections indicate that more persons disabled by DA&A will need referral and monitoring. We are evaluating the information and will come back to the Committee once that evaluation is completed.

In addition to the steps we have already taken, we need to provide additional alternatives for providing effective treatment and rehabilitation. To accomplish this, we are working with SAMHSA on joint demonstration projects, two of which were awarded in September 1993, to test alternatives for providing representative payees and for providing effective treatment and rehabilitation services to SSI recipients who are disabled by DA&A. Alternatives that will be tested include in-depth case management of these individuals, the effect of paying for some treatment, and paid representative payees.

Representative payees

I would now like to briefly mention the steps we have taken to comply with the requirement that SSI recipients disabled by DA&A receive their benefits through a representative payee. The initiatives we have implemented in this area are an important aspect of our efforts to strengthen and improve the administration of the treatment and monitoring provisions.

As I indicated earlier in my testimony, Congress provided for this requirement because of concerns that SSI recipients who are disabled by DA&A might use cash

assistance to support their addictions. Paying benefits to a responsible third party was seen as a way of meeting the recipient's basic needs, without supporting his addiction, and paying benefits to representative payees has achieved this goal to some extent. Representative payees are instructed to use benefits to provide for the recipient's basic needs, such as shelter, food, clothing, and medical care.

We believe that most payees are conscientious in trying to meet these obligations. However, this can be a difficult task in the case of some DA&A SSI recipients. Since these individuals know the amounts of their monthly payments, they sometimes manipulate or intimidate their representative payees into giving them cash.

We think that one way to strengthen the program for SSI recipients disabled by DA&A is to encourage non-profit organizations to serve as representative payees for them. Organizational payees could create a closer link between benefit payments and treatment efforts and would be less likely to yield to beneficiary pressures for cash.

We have for some time been working with community service groups to provide volunteer representative payees for beneficiaries who need them. However, it is often difficult to find volunteers willing to serve as payees for substance abusers.

In an effort to meet this need, we have begun a systematic recruitment effort aimed at professionals who serve these recipients. Last summer, we met with representatives of several organizations serving substance abusers. These included the National Association of Alcoholism and Drug Abuse Counsellors, the National Association of Addiction and Treatment Providers, the Mental Health Policy Resource Center, the National Coalition for the Homeless, and the National Coalition of Hispanic Health and Human Services Organizations. Most of these organizations have agreed to publicize the need for representative payees in their member publications. In general, the national organizations we have contacted have indicated their administrative costs are the primary barrier to providing payee services.

Another initiative affecting representative payee selection is part of the demonstration projects with SAMHSA, which I mentioned earlier. The demonstrations will attempt to address some of the difficulties encountered in selecting payees for SSI recipients disabled by DA&A by testing alternative paid sources, such as RMA's or other involved State or local agencies or organizations to receive and manage the SSI payments for recipients disabled by DA&A. Selecting the RMA or treatment provider as the representative payee, where appropriate, could more closely link continued receipt of benefits to ongoing treatment and monitoring. We are also exploring this approach in Ohio where we are working closely with the RMA and a county agency to provide payee services to SSI recipients disabled by DA&A.

Steps toward solutions

Mr. Chairman, as I have already indicated, the issues associated with substance abuse are very difficult. We have been, and will proceed, to work hard to improve our administration in these areas. I would like you to know that the Administration wants to continue working with the Congress to fully address the problems associated with treatment and monitoring for persons who are disabled by substance addictions.

In general, we support deficit-neutral legislation which we think would strengthen the program and help to ensure that it assists in the rehabilitation of persons disabled by DA&A, including some of the measures that were passed by the Senate and favorably reported by the House Ways and Means Committee. The provisions we support would:

- Require, as a condition of eligibility, that persons disabled by DA&A for Social Security disability insurance (DI) benefits participate in available treatment (as is now required in the SSI program);
- Provide for mandatory, progressive sanctions for noncompliance with available treatment for both the DI and SSI programs;
- Require that DI benefits for persons who are disabled by DA&A be paid to a representative payee (as is now required in the SSI program);
- Make permanent the authority which allows certain non-profit organizations to collect a fee from beneficiary/recipient payments for providing representative payee services, expand the universe of organizations allowed to charge a fee to include appropriate government agencies, and increase the fee amount somewhat; and
- Require gradual payment of lump-sum benefits in DA&A cases.

INTERPRETER FRAUD

Let me now turn to another issue you asked me to address—allegations of interpreters providing fraudulent information to secure SSI payments for some non-Eng-

lish speaking applicants. I want to assure you that the Administration is committed to taking the strongest possible measures to deal with fraud in the SSI disability program as well as in all the programs we administer. No one should be allowed to defraud the Government and take scarce resources away from the needy, elderly, or disabled who deserve and depend upon them so much. Fraud makes people suffer—those who speak English as well as those who do not—because it makes all applicants suspect. The program as a whole suffers as its reputation is tarnished in the eyes of the public.

Within the last couple of years, we have encountered several cases of suspected interpreter fraud in the SSI program, particularly in the Southern California area within the Southeast Asian community, and arrests have been made in these cases. (The State of California has 38 percent of the total claims workload involving non-citizens and 54 percent of the workload involving Southeast Asian claimants.)

We have already undertaken substantial efforts to prevent interpreter fraud. I think we can agree that preventing fraud must be our primary focus. However, we think that additional focus must be placed on enforcement activities. That is why we are pleased that our colleagues in OIG have been able to concentrate some of their resources on the issue of interpreter fraud, particularly in the state of California. Some of the initiatives that we currently have underway include:

- Developing public information materials, pamphlets, and factsheets in several different languages, stressing the availability of free interpreter services. We will also seek the cooperation of foreign language publications in having advertisements of a similar nature placed as public service announcements.
- Placing continued emphasis on hiring bilingual employees. Over half of all employees recently hired in field offices has been bilingual. (About 15 percent of field office interviews are conducted in a language other than English, while almost 19 percent of staff are bilingual.)
- Evaluating other alternatives for interpreter services, including a national contract for full-service telephone interpreter services.
- Ongoing communications with the leadership of foreign language communities to determine how we can best provide quality services to the non-English speaking population.
- Requiring both applicants and interpreters to sign statements regarding the accuracy of the translation and information provided. We also revised instructions to clarify field office authority to secure independent interpreter services and/or discontinue interviews when the completeness and accuracy of an interpreter's services is in question.
- Reevaluating cases in California which are already in payment status whenever fraud is suspected. We will be redoing interviews and medical development to ensure that the disability evidence presented is accurate in the first of the 2,000 cases identified in which fraud is suspected. We began this effort the week of April 11, 1994. In addition, the California DDS has already completed the redevelopment of pending applications where fraud was suspected.

We think our administrative initiatives have already improved the integrity of the SSI disability program and will continue to do so. However, we also support provisions included in the pending legislation I mentioned earlier which would strengthen the provisions for imposing civil penalties for SSI fraud.

CHILDHOOD DISABILITY

Finally, Mr. Chairman, let me address the third issue you raised—allegations that children are receiving SSI benefits on the basis of inaccurate medical evaluations. As you know, in February 1990 the Supreme Court ruled, in *Sullivan v. Zebley*, that SSA's regulations for childhood disability were too restrictive. As a result of the Court's decision, SSA developed rules that provide an individualized functional assessment of children to determine the effects of the child's impairment(s) on his or her ability to perform age-appropriate activities.

As a result of that decision, SSA was faced with tremendous workloads associated with developing new regulations and reevaluating a large number of cases covering a 10-year retroactive period. I am very proud of the efforts of SSA and DDS employees who processed this extensive workload.

Now that we have fully implemented the new childhood disability rules, we need to assess whether the new standards are being applied as the experts who developed the new rules had envisioned. We also recognize that the new rules for evaluating children with impairments may require some adjustments as we obtain more experience and knowledge. Consequently, we are providing continued oversight in this area including: national training on the regulations for processing children's SSI

claims; additional reviews of childhood allowance claims; and, increased continuing disability reviews for children receiving benefits.

OIG is currently looking at SSA's rules for determining the eligibility of children with selected mental impairments and the DDS's compliance with those rules. I understand OIG expects to issue a report on this issue within the next several months, and we will work closely with OIG to correct any identified inconsistencies in processing SSI claims for disabled children.

I believe that these oversight efforts will enable us to improve the accuracy of our evaluations of childhood disability. Part of our concern with this issue relates to allegations of parental coaching of children to behave in certain ways in order to help them qualify for SSI benefits. We recently completed a 600-case study of childhood disability claims to determine if the new regulations were being applied correctly, if there was any evidence of parental coaching, and if coaching affected the accuracy of decisions. Our study focused on conduct and learning disorder cases because they are the most susceptible to coaching and malingering. These also were the types of cases most often cited in allegations that children with "mild" impairments are being found disabled.

The study findings showed no evidence of widespread coaching or that coaching had influenced decisions. We also found that the rules governing children were generally being applied correctly by those making disability determinations. However, a small number of children with mild impairments were found disabled due to apparent misunderstandings of the guidelines in our regulations. We have issued written instructions to clarify these guidelines.

CONCLUSION

In closing, Mr. Chairman, I think that we all recognize that these are difficult issues which require careful consideration. We need to treat all individuals equitably and with compassion. However, we also need to ensure that the program is well managed and that it includes strong motivation for those disabled by DA&A who can influence recovery by their own actions to improve their condition and become self-supporting.

We will be happy to work with the Congress, other Federal agencies, advocacy groups, and other interested parties to consider approaches that will help us to provide adequate oversight of the programs we administer.

Attachments:

TOTAL NUMBER OF SSI BLIND/DISABLED AND PERSONS MEDICALLY DETERMINED DISABLED BY DRUG ADDICTION AND ALCOHOLISM BY NUMBER AND PERCENT

[SSI blind/disabled recipients aged 18-64]

Year	Total	DA&A recipients	
		Number	Percent of total
1975	1,678,000	10,000	0.6
1976	1,686,000	9,000	.5
1977	1,730,000	6,000	.3
1978	1,706,000	5,000	.3
1979	1,680,000	4,000	.2
1980	1,686,000	5,000	.3
1981	1,669,000	4,000	.2
1982	1,618,000	4,000	.2
1983	1,661,000	3,000	.2
1984	1,775,000	4,000	.2
1985	1,840,000	5,000	.3
1986	2,021,000	7,000	.3
1987	2,128,000	10,000	.5
1988	2,215,000	13,000	.6
1989	2,318,000	17,000	.7
1990	2,462,000	24,000	1.0
1991	2,604,000	34,000	1.3
1992	2,859,000	54,000	1.9
1993	3,071,000	79,000	2.6

SSI DEMOGRAPHICS OF BLIND/DISABLED AND PERSONS MEDICALLY DETERMINED DISABLED BY DRUG ADDICTION AND ALCOHOLISM

Recipient profile	Percentages	
	Total SSI blind/ disabled ¹	SSI DA&A ²
Age:		
18-29	18	10
30-39	23	34
40-49	21	35
50-59	23	18
60-64	15	3
Gender:		
Male	44	71
Female	56	29
Type of representative payees:		
Relative	71	60
Social agency	7	4
Mental and nonmental institutions	11	1
Other	11	35
Geographic breakdown: ³		
California	16	33
Illinois	5	17
Michigan	4	10
New York	9	4

¹ Includes SSI blind and disabled recipients aged 18-64, as of December 1993.

² Includes SSI recipients disabled by drug addiction and alcoholism aged 18-64, as of December 1993.

³ States with highest percentage of SSI DA&A recipients.

Senator HARKIN. Thank you very much. I was not anticipating that statement on bonuses. I am aware of the article that came out in the Washington Post about that performance award.

How long has Dr. Thompson worked for the Federal Government?

Dr. CHATER. How long has he been with SSA?

Senator HARKIN. The whole Federal Government.

Dr. CHATER. A lifetime, forever. [Laughter.]

Senator HARKIN. I do not know Mr. Thompson. Has he been in the Government 5 years or 10 years or more?

Dr. CHATER. It is more like 15 to 18 years.

Senator HARKIN. And you refer to him as Dr. Thompson?

Dr. CHATER. Yes, sir.

Senator HARKIN. And why do you refer to him as Dr. Thompson?

Dr. CHATER. He has a Ph.D., in economics.

Senator HARKIN. He has a Ph.D., in economics. He has worked that long for the Government. His bonus was a \$9,256 bonus.

Well, I just want to state for the record that I do not know anything more about the case than what you just said and what I read in the paper. I do not know Mr. Thompson. I never met him. I do not know what his performance has been like.

But if his performance has been as you have indicated and he has the level of achievement educationally and has been a good public servant I just do not see that as being out of line, and I will state that publicly. I mean, I happen to give bonuses to my staff. I think it is a good thing to give bonuses to hold things up and to say, OK, if you perform well and other staff and other people can see why that person got a bonus, because this is what he or she did, there is nothing wrong with that. And I feel badly that Mr.

Thompson has to feel that he in conscience has to return this money.

Again, I do not know about the entire case. Again, operating on the assumption and on the basis of what you have said here about his background, his level of education achievement, his performance in SSA and GAO before that, I see no reason why he should have to return that money.

Dr. CHATER. I appreciate your comments, Mr. Chairman. There is a question, however, about the number of days for which he worked for SSA. He was employed for approximately 2½ to 3 months as the Acting Commissioner, and, therefore, had not been with the Social Security Administration for a long enough time to receive an award from us.

Senator HARKIN. Why cannot GAO give him a bonus?

Dr. CHATER. Let me make it very clear that I value his performance highly, and I rated it extraordinarily meritorious during my observations of him as he was Acting Commissioner and subsequently as I have worked with him on a day-to-day basis.

On the other hand, I do not wish to do anything that is against our guidelines or regulations. And because of the sensitivity of this issue we both felt that it was just better for him to return the bonus. He has volunteered to do that, and I hope that will bring an end to this discussion.

Senator HARKIN. Well, fine, I will leave it there. I think more investigation needs to be done in this. I note that one of my colleagues has raised this as an issue, that bonuses are given out like candy as a matter of routine rather than as an award for truly outstanding work. Well, if that is the case then I agree with my colleague.

If it is given out for performance and achievement, then that is quite another thing. That is the point I want to make is if in fact that person had achieved or had performed I see nothing wrong with it.

But I will leave it there, and I will yield to my colleague, Senator Bond.

Senator BOND. Thank you very much, Mr. Chairman. Mr. Mangano, I apologize. I was called away and I came in in the middle of your testimony. I have reviewed the written testimony on behalf of Inspector General Brown, and I note that you stated that tying payments to treatment would be a strong disincentive for recipients to succeed in rehabilitation. Even those who do succeed at DA&A rehabilitation may face a difficult task of finding employment.

The reason I am concerned about that is I look back on the previous page under your statement entitled, minimal positive outcomes from current treatment requirements. Recent analysis of a sample of 197 drug addicts and alcoholic recipients found that after more than 3 years most continue to receive SSI.

For the 24 that stopped receiving, one-half had died, 20 percent had become ineligible, 10 percent were imprisoned, and only 1 of the 197 recipients left SSI rolls due to significant earnings or medical improvement.

It seems to me when you have a program where you are succeeding with one and roughly 19 to 20 are going to prison, is there not something wrong with that program?

Mr. MANGANO. I think maybe my testimony is a bit confusing. When I say it is a disincentive to get cured, I am talking about it being a disincentive to the person who wants to maintain themselves on that roll, because it is a payment they are receiving. I do not mean to imply that we believe you ought not to have some incentive built into the program to get people cured and, therefore, off of the rolls and reemployed.

Senator BOND. Would a time limit make sense, because I mean, if you continue to treat people for 3 years and they are no better, it does not seem like it is a good expenditure of money, does it?

Mr. MANGANO. I think the professionals need to decide what is the appropriate kind of treatment for people and what should be the expected outcomes of that treatment. There ought to be sanctions built in the process to establish the sort of treatment, the oversight of that treatment to ensure that the persons are receiving the treatment they are supposed to be getting, and making proper progress toward their treatment. When they fail to do that, as in some cases where people stop going to treatment, there ought to be sanctions applied against that.

I know the Social Security Administration is developing proposals right now that would go very much along those lines.

Senator BOND. The chairman and I have introduced a welfare reform measure that essentially requires a responsibility on behalf of the recipient that they sign a contract, and if they do not sign a contract, or if they sign a contract and do not live up to the terms of that contract, their payments are reduced, and then after a period of time they are completely cut off. Is there any reason why that same approach ought not to apply in SSI?

Mr. MANGANO. We would be very supportive of that kind of approach, where it has incentives and sanctions built into it.

Senator BOND. Because as I mentioned in my opening statement, clearly this is a program that is beginning to engender a tremendous amount of negative reaction.

I read just one case that happened to deal with a childhood recipient. Anecdotal evidence, to be sure, but there are more and more of these cases coming into our office, and I am sure this has happened to all of my colleagues.

We could provide you with a long list of these statements, and it is my view that something radical needs to be done with the program to make sure that those who need the benefits actually receive them, and that those who either do take advantage of the system, abuse the system, or continue to exist in a condition which we had hoped to raise them out of will get out of the system.

Are there specific proposals that you would have from the inspector general's side on that?

Mr. MANGANO. Well, there are recommendations we have made in the past that are important. First, that there be a better definition of what being alcohol or drug-dependent is. The Wilkerson court helped to determine that quite a bit, and the Social Security Administration has been putting out increased guidance to decide what that is.

The most important recommendation we had made back a couple of years ago dealt with the referral and monitoring agencies to make sure that there were people monitoring the treatment programs of these individuals.

At the time we had done our earlier study, we found about 8 percent of the persons were listed in Social Security records as being in treatment, and in fact, as Dr. Chater also pointed out in her testimony, the referral and monitoring agencies that were supposed to keep track of these individuals did not really exist.

In 1990, there were only 15 of them across the country. Today, there are 34. I believe by the end of the fiscal year they will exist in every State.

So the important element here is having an organization track persons in their treatment and report back to Social Security when persons are falling out of compliance is really critical.

We would also endorse the notion, as I have mentioned before, that there be sanctions in the process so that when an individual decides not to comply with their treatment program or the requirements the Social Security Administration puts on them, there will be sanctions applied.

Some of those sanctions could be termination from the program for short periods of time until the person came back and assured the program that indeed they were back into treatment and doing fine. There could be progressive sanctions, to the point where SSA eliminates the person from the rolls.

There ought to be a continuous disability review. The persons that were in the program were not under a continuous disability review. That is a review from time to time to again look at the disabling condition to see what appropriate action should be taken.

Unfortunately, the Supplemental Security Income Program has not been able to conduct those kinds of reviews since about 1989.

Senator BOND. Well, does it not seem like we have just opened the spigot if we are paying out funds we cannot monitor? You know, I am shocked by the small sample you took, because it is clear why we are getting complaints about it, if there is no monitoring. We are paying out money and apparently having no impact, because there is not a mechanism in place.

Regarding SSI interpreter fraud, let me ask you on criminal remedies, you say it is difficult to obtain witnesses. Apparently from your testimony there is a lack of accountability in the system which would allow criminal behavior to be pinpointed. Do you have recommendations on how criminal penalties could be—and this is in the interpreter section—that there could be specific responsibilities placed on these people so they could be found guilty?

In the work I have seen, the only way you can impose criminal penalties is to define clear-cut responsibilities. Do you have recommendations on that?

Mr. MANGANO. The section you are referring to deals with the interpreter fraud in which interpreters acting as middlemen have infiltrated some of the non-English-speaking communities in the country, particularly Southeast Asians. The allegations are that they are conspiring with physicians to make sure that potential beneficiaries, primarily immigrants and refugees, become eligible for supplemental security income.

In those cases, there are some criminal penalties we can apply against them, but they are very detailed, and take a long period of time to actually bring to fruition. We have supported a recent proposal from Social Security that would allow them to create a more streamlined civil money penalty. If that were put into place, we could take action far more quickly against the interpreters or the medical providers that were committing those kinds of crimes.

Senator BOND. I would certainly encourage that, but are there legislative changes that are needed, or are there primarily administrative changes so you can develop the evidence on which to bring a criminal case?

Mr. MANGANO. The civil money penalty would require legislative action, and language I believe has been put into a Ways and Means Subcommittee report on this issue.

Senator BOND. Would that also facilitate fixing responsibility for criminal liability?

Mr. MANGANO. I believe it would.

Senator BOND. Dr. Chater, I have asked a great number of questions from the inspector general side. Since this is your area, I would ask you for your comments on these questions and how you view these problems, and what direction you feel we can take to assist you in dealing with what seems to be some very, very wide-open areas where abuse may be occurring.

Dr. CHATER. Well, I think the legislative language that will come before Congress will be helpful to us, but I would also like to share with you some of the efforts that the Social Security employees are now engaged in to deal with the prevention of interpreter fraud. We think if we prevent it at the front end, obviously we will not have to deal with it later.

I personally visited the Anaheim, CA, district offices a week or so ago to see first-hand how our employees are dealing with this, and we have a number of initiatives in place. The very first one, and most important, is that Social Security is providing its own interpreters, so we will not have the middle man necessity that we have had before.

We are also working to see how we can find a particular translator that will be a Social Security-hired person if we do not have an employee who speaks that particular language. For example, 50 percent of all our new hires last year were people who could speak a language other than English, so we are making tremendous progress along that line.

In addition, the Inspector General's Office has given to us the names of claimants who allegedly received benefits because of an interpreter who was practicing fraudulent activities, and we are now in the process of reviewing each and every case. In fact, the employees were working on Saturdays to do just that, redeveloping the case to see if the allegations are indeed true, and we will take action on those when that particular process is finished.

One of the agencies in California, for example, has decided to use a camera to take photographs of the claimants, because it was alleged that one claimant was coming in several times pretending to be different people, so the photograph on a particular file will help us identify the person with whom we are dealing. These initiatives are in place to prevent fraud in the first place and to follow up on

allegations that we know of from the Inspector General's Office. We are working very closely with the inspector general to be sure we can handle this problem.

Senator BOND. Well, I think there is probably some steps that are even more effective in identifying that.

Mr. Chairman—we have our distinguished chairman of the full committee here—we will have some further questions which we will submit for the record, but we look forward to working with you on this.

I understand there is a GAO report in process on the children's program.

Dr. CHATER. That is correct.

Senator BOND. When is that due?

Dr. CHATER. That is to be completed by fall, early fall, as I remember.

Senator BOND. Well, we will look forward to working with that. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bond.

As Senator Bond indicated, we are graced with the presence of our distinguished chairman of the full committee and a member also of this subcommittee. Senator Byrd.

Senator BYRD. Mr. Chairman, thank you.

I thank you for the hard work that you do on this subcommittee, and you do an excellent job, you and the subcommittee, even though you are strapped for funds.

I would like to focus the attention of the subcommittee for a few minutes on the SSI Program, and I would like in particular to call attention to an ABC program of May 2, 1994, and the program was as follows:

Here is ABC's Linda Patilla. Linda Patilla, ABC News, in the small Arkansas town of Parken, one of the main sources of income is not from industry or farming, but from a Federal program for disabled children.

16-year-old Jimmy and his younger sister and brother receive more than \$1,200 a month in disability benefits, the disability, according to their grandmother, headaches, and fainting spells.

Across town, 12-year-old Erica and her 10-year-old brother each get \$446 a month. Their disability, according to their mother, Erica is a slow learner, and Tibaris has an enlarged liver. With their disability checks, their mother buys groceries and gives each child a \$60-a-month allowance.

Brenda Smith, mother: I make sure they get the little odds and ends and the junk food that they like to eat. I give them their little allowance, and after I give them their little allowance, then they go shopping.

Linda Patilla: This is all perfectly legal under the supplemental security income, or SSI program. Under its loose guidelines, poor children who are found to have a disability can receive up to \$446 a month, three times the average payment for a child on welfare. The guidelines are so loose and the payments so lucrative, critics say that some parents are having their normal children certified disabled.

State Representative Pat Flanagan, Arkansas legislature, is quoted as saying, people tell the children, go to school, act crazy, we'll get \$407 a month for nothing.

Linda Patilla: There is no requirement that parents use the money to treat their child's disability. Nowhere have the numbers grown faster than in Arkansas, from 6,000 children 4 years ago to 17,000 last year, at a cost of \$70 million, all Federal money. In this five-county area, which is predominantly black, the number of children tripled.

On camera, still Linda Patilla: The disability benefits have become so widespread the people who receive them now have a name for the monthly payments—crazy checks.

Linda Patilla: Last year at the elementary school in Parken, teachers were asked to process disability applications for a quarter of the school's students.

Sarah Broom, former teacher: I had a student tell me once that he didn't have to listen to what I had to say, because he got his \$450 check every month. He said that all he had to do was act crazy every once in a while.

Linda Patilla: Teachers are appalled at both the rising number of children and the early age at which they are designated as disabled.

Theresa Sanders, teacher: I have right now 7 children out of 18 that are getting the SSI checks.

Linda Patilla: In kindergarten?

Theresa Sanders: In kindergarten. Some of them got it before they came to kindergarten.

Linda Patilla: How easy is it for children to be certified as disabled when they are not?

Dr. Curtis Patton evaluates an average of eight children a week who are filing for disability. Most claim to have a mental, emotional, or a learning problem.

Dr. Curtis Patton, of the East Arkansas Children's Clinic: It is very easily coached, where the mother may have said, you know, don't answer the doctor's questions, act like you don't understand him.

Linda Patilla: The doctor notes his suspicions, but often finds out later the children were approved anyway. The head of the State agency that evaluates the claims refused to be interviewed on camera, but insisted that no widespread fraud has been found. Still, critics say there would be no incentive for fraud if the money went directly to treatment for children and not a blank check for their parents.

State Representative Pat Flanagan: I fault some people for abusing it, but I fault the United States Government as acting crazy in allowing such a system to exist.

Linda Patilla: It's simply economics. As long as the Government allows them to, many say they'd be crazy not to take advantage of it.

Linda Patilla, ABC News, in Eastern Arkansas. Peter Jennings a little later in the broadcast will have another way your money is being spent.

Did either of you see this ABC World News Broadcast?

Mr. MANGANO. I did.

Senator BYRD. What did you think about it?

Mr. MANGANO. It is a scary story. We have undertaken a number of studies in our office, and we have two major ones underway right now. I would be happy to fill you in on what we are doing in those studies because I think it does bear on the stories that that broadcast was talking about.

Senator BYRD. Would you fill the subcommittee in on that for the record?

Mr. MANGANO. Sure. We have two studies underway. One is dealing with children that have been determined to be eligible. The second one is taking a look at children who were determined not to be eligible in calendar year 1992.

There are basically two objectives of those studies. The first is to take a look at the adequacy of Social Security guidance to the States to make the determinations for children being eligible or not. The second is, how well did the States carry out that guidance. It is a 10-State study.

We are looking at case records in each of the States. We are taking out sample cases, reviewing the case files to determine whether there is medical evidence in there to support the determination or not. We are also talking with the State disability determination agency representatives to find out what they know about these particular kinds of cases.

One of the issues we are discussing is coaching. When we issue our report, we will be able to fill in the committee as to the veracity or widespread nature, or not widespread nature, of this particular problem.

We are doing basically the same kind of thing with the children who were determined not to be eligible—looking at the files to see

if the evidence indicates that the child should have been declared eligible. We anticipate having the first of the series of reports completed in draft by the end of June and the last of the reports issued in draft in September.

We are also taking a look at the case files to see what kinds of services the children were receiving before they became Zebbley-eligible. For example, the AFDC Program (Aid to Families With Dependent Children) or the Medicaid Program?

It is important to determine the kinds of services they were receiving before they became Zebbley-eligible to see what happened afterward. Did anything happen with their Medicaid records? Were they continuing in treatment? Did they stop treatment? What kinds of treatments were they receiving?

Senator BYRD. I call attention to a February 4, 1994, item in the Washington Post. Title: "Costs Soar for Children's Disability Program. How 26 Words Cost the Taxpayer Billions in New Entitlement Payments, byline, Bob Woodward, Benjamin Weiser, Washington Post staff writers." I hope I have not mispronounced the name.

Now, looking at the body of the story, just quoting excerpts from it:

Norah Cook Porter, a pediatrician and lawyer, works on the front lines of the Nation's entitlement system. She can barely contain her frustration as she flips through some of the thousands of applications for a Federal aid program for disabled poor children that have passed through her Harrisburg, PA office over the last 2 years. The files show, she says, "that children who curse teachers, fight with classmates, perform poorly in school, or display characteristics of teen rebellion, are often diagnosed with behavioral disorders and, therefore, qualify for the program's cash benefits, which average \$400 a month."

Under a broad new Federal standard prompted by a 1990 Supreme Court ruling, behavior that isn't "age appropriate" is considered a disability. Porter feels her hands are tied by the new rules. She has tried to block benefits to children who, in her medical opinion, are not suffering from any disability. Her superiors have overruled her, and she has written detailed rebuttals. Last month, she was suspended without pay for her repeated protests, and she believes her job as a disability review physician is in jeopardy.

What can happen. The history of the children's disability program illustrates what can happen when a law is enacted without much debate or study and then becomes subject to interpretation by regulators, advocates, and the Supreme Court.

The new age-appropriate standard that Porter criticizes was written by Federal regulators after the Supreme Court ruled that the law required the Government to use a broader definition of disability in determining eligibility.

Since the Court ruling, the number of children receiving benefits has more than doubled. The decision also led to lump-sum back payments for some 150,000 children who had been denied benefits under the old rules. These back-payments—which averaged \$15,000, with some as high as \$75,000—have cost the Government \$2 billion since 1991, plus at least \$287 million more in administration.

Parents or guardians are not required to use the money for therapeutic or medical aid. They can spend the cash payment as they please as long as it benefits the child in some way. That rule has been interpreted to allow the purchase of a television set—

Just what they do not need. That was editorial comment by me. It was not a part of the extract from the item.

A video game, or a car.

More of what they do not need.

Families receiving the back-payments were required to spend the money within 6 months, so that their sudden wealth would not make them ineligible for the income-based program.

Thomas C. Joe, a senior Federal welfare official, inserted the 26-word clause that expanded SSI to cover children. It appeared in parentheses, as follows: (or in the case of a child under the age of 18, if he suffers from any medically determinable physical or mental impairment of comparable severity).

This gentleman, according to the article, is now head of a Washington social policy think tank. He said that:

Expanding the program to cover disabled children was part of his "incremental strategy" to assist as many poor people as possible. It was a welfare program disguised as disability assistance.

There was no consideration of the financial or policy consequences of other ways to aid disabled children, according to participants in drafting the original legislation, nor was there any public hearing that even mentioned Joe's 26-word clause.

Joe acknowledged with some humor that he tucked the provision into the 697-page bill in order to sneak it through.

The chairman at that time, Chairman Russell Long, "made a run at killing the provision." What happened in conference is not known.

The 67-page report from the conference made no mention of how the issue was settled.

With reference to the Supreme Court case:

In 1990 in *Sullivan v. Zebley*, the Supreme Court ruled 7 to 2 in Zebley's favor and ordered the Social Security Administration to give children the same individual analysis as adults.

To implement the high court's ruling, the agency asked a panel of experts to settle the question, what is the worth of a child?

The panel's answer, in the form of new regulations, is the primary cause of Nora Porter's complaints. That was the lady whose name is mentioned at the beginning of the article, a pediatrician and lawyer.

The new rules defined a child as disabled if his impairments "substantially reduce" his ability to "grow, develop, or mature physically, mentally, or emotionally, and thus to engage in age-appropriate activities of daily living."

These activities ranged from learning, communicating, and performing in school to interacting appropriately with peers and family members.

Social Security officials said the panel was seeking a common-sense way of comparing children and adults. In Porter's view—again referring to the pediatrician—they failed. "Age-appropriate is a fictitious standard," she said. "It applies to the perfect child, and any deviation from that allows someone to apply for and likely be declared disabled."

There was a Harvard Medical School—I am mistaken about that. There was a lawyer, if I can find his name—Jonathan Stein, a legal services lawyer in Philadelphia, whose vigorous and passionate attention and advocacy were drawn to the case as it wound its way through the Federal courts, and he and a colleague, Richard Weishaupt, took Zebley's case all the way to the Supreme Court.

Stein regularly threatened to seek contempt-of-court citations when he felt the Social Security Administration wasn't implementing the rules fast enough.

One of Stein's most significant accomplishments was getting Social Security to review roughly 450,000 cases, dated to 1980, in which children had been denied benefits. This led to the 150,000 lump sum back payments.

The rules legitimized and even encouraged shopping sprees. Here's one lady who used the money to buy a car, a washer and dryer, a refrigerator, a stove, a television, a \$2,500 computer, and three jogging suits for her son.

She also repaired her bathroom, leaky roof, and collapsed hallway floor, some of which probably at least needed some attention.

The Social Security Administration does require an accounting from the person who is entrusted with the child's check, but the agency does not have the resources to scrutinize spending on a large scale.

But to address all these complicated questions, the Government has now written some 40,000 words to interpret Tom Joe's original 26-word phrase.

Mr. Chairman, I ask that the entire article, which appeared in the Washington Post, appear in the record of the hearings.

Senator HARKIN. Without objection.

[The information follows:]

[From the Washington Post, Feb. 4, 1994]

COST SOAR FOR CHILDREN'S DISABILITY PROGRAM: HOW 26 WORDS COST THE TAXPAYERS BILLIONS IN NEW ENTITLEMENT PAYMENTS

(By Bob Woodward and Benjamin Weiser, staff writers)

Nora Cooke Porter, a pediatrician and lawyer, works on the front lines of the nation's entitlement system. She can barely contain her frustration as she flips through some of the thousands of applications for a federal aid program for disabled poor children that have passed through her Harrisburg, Pa., office over the last two years.

The files show, she says, that children who curse teachers, fight with classmates, perform poorly in school or display characteristics of routine rebellion are often diagnosed with behavioral disorders and therefore qualify for the program's cash benefits, which average \$400 a month. Under a broad new federal standard prompted by a 1990 Supreme Court ruling, behavior that isn't "age appropriate" is considered a disability.

Porter feels her hands are tied by the new rules. She has tried to block benefits to children who, in her medical opinion, are not suffering from any disability. Her superiors have overruled her, and she has written detailed rebuttals. Last month, she was suspended without pay for her repeated protests, and she believes her job as a disability-review physician is in jeopardy.

Months before her suspension, she agreed to be interviewed because she believes that the children's disability program is an example of an entitlement system gone haywire. She hopes that her decision to speak out will draw attention from congressional or federal investigators.

The age-appropriate standard is only the most recent flaw in the program, according to Porter and others. They trace the program's problems to its origin: a vague, little-debated 26-word clause that was hastily inserted in a mammoth welfare bill passed in 1972.

Porter's criticisms are echoed by many others who work in the program. They say they sympathize with the children, many of whom are living in desperate poverty. But, they argue, the program does little to help them with their real troubles, especially since the majority of children who now qualify have mental disorders rather than physical ones.

How to provide for the country's neediest—the old, the young, the poor, the sick, the disabled, the disadvantaged—without bankrupting the Treasury has become one of the central governing questions of our time.

Earlier this week, The Washington Post published a series of articles on the rising cost of Medicaid, the health insurance program that is the government's largest entitlement for the poor. This article examines the little-known children's disability program, another entitlement for the poor, which is experiencing the same skyrocketing costs as Medicaid.

Last year, the children's disability program cost \$3.6 billion. It was serving 770,000 at the end of December, a number that none of its sponsors imagined possible when it was enacted 20 years ago, they say. Because disability recipients automatically qualify for Medicaid, the program's rapid expansion also has led to hundreds of millions of dollars in additional costs for that entitlement program.

Children's disability is a component of a larger entitlement program called Supplemental Security Income, or SSI, which provides benefits to poor people who are elderly, disabled or blind. By law, entitlement programs guarantee government benefits to anyone who meets the qualifications set out in legislation or in regulations. Federal spending levels are mandatory, meaning they cannot be altered unless the law is changed.

WHAT CAN HAPPEN

The history of the children's disability program illustrates what can happen when a law is enacted without much debate or study and then becomes subject to interpretation by regulators, advocates and the Supreme Court.

The new age-appropriate standard that Porter criticizes was written by federal regulators after the Supreme Court ruled that the law required the government to use a broader definition of disability in determining eligibility.

Since the court ruling, the number of children receiving benefits has more than doubled. The decision also led to lump-sum back payments for some 150,000 children who had been denied benefits under the old rules. These back payments—which averaged \$15,000, with some as high as \$75,000—have cost the government \$2 billion since 1991, plus at least \$287 million more in administration.

In a survey of state disability determination directors conducted last summer, more than half cited "inappropriate use of SSI funding" as the most common concern in their states. Parents or guardians are not required to use the money for therapeutic or medical aid. They can spend the cash payment as they please, as long as it benefits the child in some way. That rule has been interpreted to allow the purchase of a television set, a video game or a car.

"I really have to grapple with the idea that I'm allowing that parent to use the money any way they want to, fairly certain, given the history, that the child is not going to benefit," said a psychologist in the Washington disability determination office. "And that happens to us * * * eight times a day."

The lump-sum payments revealed what both supporters and critics of the program see as the absurdity of federal spending rules. Families receiving the back payments were required to spend the money within six months so that their sudden wealth would not make them ineligible for the income-based program.

Last summer, a group of disability experts and officials met in Washington to discuss the mission of the children's disability program. According to a confidential memo about the July 19 meeting, a congressional staff director "questioned exactly what we were trying to accomplish by giving disabled children benefits."

The response: "From a social policy perspective," the memo said, "it was interesting that no one really had a good answer"—not the policy experts, nor the people who run the program, nor even the people who oversee the legislation.

A CONSOLATION PRIZE

The children's disability program began in 1972 as a kind of consolation prize.

The Senate had just killed the Nixon administration's proposal for a guaranteed minimum income for poor Americans. As a compromise, Congress established SSI to provide aid for the "deserving poor": the elderly, blind and disabled. Initially, no money was set aside for children.

Thomas C. Joe, a senior federal welfare official, inserted the 26-word clause that expanded SSI to cover children. It appeared in parentheses, as follows: "(or, in the case of a child under the age of 18, if he suffers from any medically determinable physical or mental impairment of comparable severity)."

Joe, 58, now head of a Washington social policy think tank, said that expanding the program to cover disabled children was part of his "incremental strategy" to assist as many poor people as possible. It was a welfare program disguised as disability assistance.

There was no consideration of the financial or policy consequences or of other ways to aid disabled children, according to participants in drafting the original legislation. Nor was there any public hearing that even mentioned Joe's 26-word clause.

Joe acknowledged with some humor that he tucked the provision into the 697-page bill in order to sneak it through. "I was afraid that too many people were going to discover this and it would be a big controversy," he said. "This is a good example of democracy not at work," he added.

The Senate Finance Committee chairman at the time, Russell B. Long (D-La.), made a run at killing the provision. "Disabled children's needs for food, clothing and shelter are usually no greater than the needs of non-disabled children," his staff wrote in a Sept. 26, 1972, committee report. It said disabled children needed health care and rehabilitative services, not money, and noted that Medicaid already covered poor children's health costs in 48 states.

During the closed-door, marathon weekend House-Senate conference in October 1972 to reconcile different versions of the bill, hundreds of other welfare, Medicaid and Medicare issues were being resolved, and SSI received little attention.

"It wasn't thought of as a big deal," said Frank Crowley, a now-retired senior staffer who worked on the bill. "It was one of these annoying little details."

The 67-page report from the conference made no mention of how the issue was settled. J. William Kelley, a House Ways and Means Committee staffer at the time, has a copy of the only existing conference paper about Senate amendment No. 564, which called for dropping Joe's provision. The single sheet reads: "CONFIDENTIAL. Summary: The House bill authorizes payments to children under age 18. The Senate bill does not." The line under "Cost" was left blank.

When the conference report was presented to the House on Oct. 17, 1972, Rep. Phillip Burton (D-Calif.) rose to praise the new program. "Thanks to Tom Joe, this is now a reality," he said.

WHAT IS DISABILITY?

Joe's amendment became law without anyone addressing the obvious question: How do you define disability for a child?

Previously, disability assistance had been premised on the disabled person's inability to work. The purpose was to make up for lost income. The bill creating SSI defined a disabled adult as someone "unable to engage in any substantial gainful activity."

But children don't work, at least until they become teenagers. "It is ludicrous on its face to apply the same standard to children," said Joseph Humphreys, a former congressional staffer who worked on the 1972 bill. Humphreys called the 26 words "a punt by Congress" that left regulators to decide what to do.

The meaning of Joe's 26 words—especially the phrase "comparable severity"—has been controversial ever since. Even today, Joe said, he doesn't know exactly what the phrase was supposed to mean.

In writing regulations, the Social Security Administration, which runs SSI, said an adult was eligible if his or her disability appeared on a predetermined list of physical and mental impairments. If it didn't, the adult could still qualify by having a personal evaluation that determined that he or she was unable to work.

The regulations treated children differently. They had to manifest one of the listed impairments, such as acute leukemia, chronic epilepsy or serious mental retardation. Because children generally don't hold jobs, individual evaluations were not considered necessary.

In the early 1980's, the Reagan administration moved to slash the number of people on federal assistance programs, including SSI. One of the thousands of people affected was Brian Zebley, a 5-year-old retarded boy. His family filed a lawsuit, charging that the government was illegally denying benefits to Brian and other children.

As the case wound its way through the federal courts, it attracted a vigorous and passionate advocate—Jonathan Stein, a legal services lawyer in Philadelphia. The legal counterpart to Joe, Stein saw the courts as a way to extend benefits to the poor. He and a colleague, Richard Weishaupt, took Zebley's case all the way to the Supreme Court.

Stein spotted the logical flaw in the administration's way of determining eligibility: The "comparable severity" test could not be applied to children unless the methods of assessing disability in adults and children were themselves comparable. Children deserved the same kind of individual assessments that adults were receiving, Stein argued.

A Supreme Court case often carries the expectation that large constitutional, moral or social issues will be addressed. The Zebley case, however, was framed narrowly: Had the government properly interpreted the law? In 1990, in *Sullivan v. Zebley*, the Supreme Court ruled 7-2 in Zebley's favor and ordered the Social Security Administration to give children the same individual analysis as adults.

To implement the high court's ruling, the agency asked a panel of experts to settle the question: What is the work of a child?

The panel's answer, in the form of new regulations, is the primary cause of Nora Porter's complaints. The new rules defined a child as disabled if his impairments "substantially reduce" his ability to "grow, develop or mature physically, mentally or emotionally and thus to engage in age-appropriate activities of daily living." These activities ranged from learning, communicating and performing in school to interacting appropriately with peers and family members.

Social Security officials said the panel was seeking a common-sense way of comparing children and adults. In Porter's view, they failed. "Age appropriate is a fictitious standard," she said. "It applies to the perfect child, and any deviation from that allows someone to apply for and likely be declared disabled."

James Perrin, a Harvard Medical School pediatrician who helped develop the regulations, said Porter's criticism was unrealistic and out of touch. He said physicians need some standard to assess a child's behavior. "None of us can think about children without raising the question of age-appropriate behavior," he said. "There's no way of approaching children and adolescents without thinking about that."

VICTORY PROVIDES LEVERAGE

Stein's legal victory gave him enormous leverage over the children's disability program. According to federal and state officials, he became the program's *de facto* supervisor.

Stein regularly threatened to seek contempt-of-court citations when he felt the Social Security Administration wasn't implementing the rules fast enough. He also provided the news media with information on how the agency's foot-dragging was costing hundreds of thousands of disabled children money that the Supreme Court said they deserved.

One of Stein's most significant accomplishments was getting Social Security to review roughly 450,000 cases, dating to 1980, in which children had been denied benefits. This led to the 150,000 lump-sum back payments.

But not even Stein could do anything about the government's requirement that the recipients spend the money within six months to remain eligible for the program. Stein unsuccessfully tried to create an exception for back payment recipients, calling the rule "Kafkaesque."

The rules legitimized and even encouraged shopping sprees. In a case that both federal officials and program advocates said was fairly typical, Beverly Smith of Greenville, Ky., received a back payment in 1992 of \$13,000 for her 11-year-old son, who is hyperactive and was deemed disabled under the new rules. Smith, who earns about \$8,000 a year sweeping up in a local bank, said she was shocked to receive so much money at once.

She used the money to buy a car, a washer and dryer, a refrigerator, a stove, a television, a \$2,500 computer and three jogging suits for her son, she said in a recent interview. She also repaired her bathroom, leaky roof and collapsed hallway floor.

The computer, she said, has helped her son to sit still for long periods of time for the first time in his life. The stove had to be fitted with protective glass doors because her son once started a fire in the kitchen.

Smith now receives a regular monthly SSI check from the government for \$446, in addition to Medicaid benefits.

In other cases disability money—both the back payments and the monthly checks—has been spent on everything from medical expenses not covered by Medicaid to family vacations. In some cases, families have tried to avoid the spending sprees by establishing trust funds for the children, but such arrangements are legally complex and prohibitively expensive.

The Social Security Administration does require an accounting from the person who is entrusted with the child's check. But the agency does not have the resources to scrutinize spending on a large scale. A guardian is suspended only if an egregious misuse of the money is called to the agency's attention.

"When you get into programs like this," said Louis D. Enoff, a 30-year veteran of the Social Security Administration and its acting director until July 1993, "if you write something that's very, very tight, then you have great difficulty * * *. You're going to have to follow up with a tremendous administrative detail to follow it through. What are we going to do? Follow every penny and ask for check stubs? And go see the evidence?"

Enoff said he wasn't sure a purchase such as a car should be allowed. "Yeah, they may buy a new car, but it's not a Mercedes or something," he said. "That's probably benefiting the kid as much as anything, because he needs treatment and he gets better treatment * * *. If the child has to go to the hospital once a week, they're taking a cab now. So you pay for the car pretty quickly." He added, "I mean, I would not buy a car, maybe, if it was me."

Social Security officials said the evidence of abuse is small. "I believe that most people are honest people * * * who really care about their kids," said Barry Eigen, a senior Social Security official. "They're not trying to beat somebody out of something. They need this."

FRACTURED ADMINISTRATION

Administration of the child disability program is divided among state and federal offices in a vast, fractured system where hardly anyone is responsible for seeing the big picture.

First, applicants visit federal Social Security offices, where financial eligibility for the program is determined. Then, the applications are sent to separate state offices, such as the one where Porter works in Harrisburg. The state offices determine medical eligibility. Finally, the cases return to the Social Security offices, which make the monthly payments and oversee the spending of the money.

Doctors and examiners in the state offices make their judgments on the basis of applications and medical assessments. They almost never meet the children they are evaluating or the parents who are spending the money. "Our work begins in the mailroom when we receive a file and ends in the mailroom when we send it back with an allowance or disallowance," said Myrtie Adkins, the Maryland office director.

Meanwhile, the Social Security officials who see the applicants have no input on the disability determination. "We don't question the decision," said Ruby Burrell, head of the Camp Springs, Md., Social Security office. "We don't even question if

they are really disabled. It would be improper to do that * * *. You meet the criteria, you get the benefits."

Many recipients come from troubled families, where parents or guardians may have their own additions or pathologies.

Karen Bolewicki, a senior examiner in Maryland for eight years, said "at least one-third" of her cases involve families in which a parent is a drug or alcohol abuser. And Maryanne Bongiovani, a psychologist in Maryland for five years with a Ph.D., said a quarter of the 4,000 children's cases she has reviewed involve sexual abuse by a family member.

Kenneth R. Carroll, a psychologist with a Ph.D. and a former colleague of Porter's in Pennsylvania, said these troubled family situations made him uncomfortable approving certain applications. "Many of the problems these children manifest are largely traceable to parental neglect or abuse," said Carroll. "Behavioral and emotional problems or conduct disorders that are directly attributable to inadequate parenting are being called disabilities, and the parents are receiving a cash award for having achieved the problem."

But Leslie Ellwood, a pediatrician with Virginia's office of disability determination, said just because a disability stems from poor parenting doesn't mean the children do not deserve assistance. "You don't want to visit the sins of the parents on the child," Ellwood said.

To address all these complicated questions, the government has now written some 40,000 words to interpret Tom Joe's original 26-word phrase. "We're doing a lot here based on one little statement," said Louis Enoff. "And is this really what was meant?"

Researcher David Greenberg contributed to this report.

Senator BYRD. Now, let me just read excerpts from a letter which was written to me on May 2, 1994.

I want to talk to you about an issue which is probably the most insurmountable obstacle I have to face as a teacher. This is a teacher in West Virginia public schools.

In addition to students who think of only welfare benefits as their future livelihood, students now are rewarded monetarily for disruptive behavior and lack of any effort by supplemental security income—SSI payments.

Students who are placed in a special education program at school can apply for these benefits and receive over \$400 per month. The resulting situation is that many students know the "racket" and deliberately try to fail and be extremely disruptive so they can test into special education and receive a check. \$400 must seem like an enormous amount to an eighth-grader.

Parents in special education meetings have expressed anger when their child does not show a need to be placed in the special education program so it can qualify for the \$400 payment.

Upon investigating the problem

Now, this is a teacher in West Virginia.

I found that it may stem from the United States Supreme Court's interpretation of 42 U.S.C.S. 1382 C.A.3, *Sullivan v. Zebley*, 493 U.S. 521 107 L.Ed.2d. 967, 110 S.Ct. 885 1990.

So she had gone to some length to research this case.

In this decision, the Court held that current Social Security eligibility requirements for disability benefits for children were "facially invalid." In essence, it expanded the indicators for eligibility.

Now, I don't know whether that word facially means factually or whether it may be a typo.

I was told by an employee at the Social Security Administration that many back pay checks were issued in the thousands of dollars, people who had applied for this benefit for their child and been denied. This money helped to advertise the decision, and the abuse has snow-balled.

Now, I have children who sit in class and do absolutely nothing. They will not participate in any class activity, and will not even put their name on a piece of paper. They are abusive to the students and teachers, and when asked what they plan to do in the future, many will readily answer, I'm going to get my SSI.

If you wish further information, please do not hesitate to contact me. The effects of this problem are devastating to our Nation, removing incentives for learning,

eroding the work ethic, and using funds intended for truly disabled children in a wasteful if not fraudulent manner.

Any help you can provide would be greatly appreciated. Thank you very much.

Mr. Chairman, I ask unanimous consent that the Federal Code of Federal Regulations, that portion that is pertinent to the subject matter, be included in the record at this point.

Senator HARKIN. Without objection.

[The information follows:]

[FROM THE CODE OF FEDERAL REGULATIONS, 20 CFR, CHAPTER III,
PART 404, SUBPART P]

APPENDIX 1 TO SUBPART P—LISTING OF IMPAIRMENTS

APPENDIX 1 TO SUBPART P—LISTING OF
IMPAIRMENTS

The body system listings in parts A and B of the Listing of Impairments will no longer be effective on the following dates unless extended by the Secretary or revised and promulgated again.

1. Growth Impairment (100.00): December 6, 1996.
2. Musculoskeletal System (1.00 and 101.00): June 6, 1996.
3. Special Senses and Speech (2.00 and 102.00): December 4, 1998.
4. Respiratory System (3.00 and 103.00): October 7, 2000.
5. The cardiovascular system listings (4.00 and 104.00) within 4 years. Consequently, the listings in this body system will no longer be effective on February 10, 1998.
6. Digestive System (5.00 and 105.00): December 5, 1997.
7. Genito-Urinary System (6.00 and 106.00): December 5, 1997.
8. Hemic and Lymphatic System (7.00 and 107.00): December 6, 1995.
9. Skin (8.00): June 6, 1997.
10. Endocrine System and Obesity (9.00) and Endocrine System (109.00): June 6, 1997.
11. Multiple Body Systems (110.00): July 2, 1998.
12. Neurological (11.00 and 111.00): June 5, 1998.
13. Mental Disorders (12.00): August 28, 1994.
14. Mental Disorders (112.00): December 12, 1995.
15. Neoplastic Diseases, Malignant (13.00 and 113.00): December 6, 1995.
16. Immune System (14.00 and 114.00): July 2, 1998.

Part A

Criteria applicable to individuals age 18 and over and to children under age 18 where criteria are appropriate.

Sec.

- 1.00 Musculoskeletal System.
- 2.00 Special Senses and Speech.
- 3.00 Respiratory System.
- 4.00 Cardiovascular System.
- 5.00 Digestive System.
- 6.00 Genito-Urinary System.
- 7.00 Hemic and Lymphatic System.
- 8.00 Skin.
- 9.00 Endocrine System and Obesity.
- 10.00 (Reserved)
- 11.00 Neurological.
- 12.00 Mental Disorders.
- 13.00 Neoplastic Diseases, Malignant.
- 14.00 Immune System.

1.00 MUSCULOSKELETAL SYSTEM

A. *Loss of function* may be due to amputation or deformity. Pain may be an important factor in causing functional loss, but it must be associated with relevant abnormal signs or laboratory findings. Evaluations of musculoskeletal impairments should be supported where applicable by detailed descriptions of the joints, including ranges of motion, condition of the musculature, sensory or reflex changes, circulatory deficits, and X-ray abnormalities.

B. *Disorders of the spine*, associated with vertebrogenic disorders as in 1.05C, result in impairment because of distortion of the bony and ligamentous architecture of the spine or impingement of a herniated nucleus pulposus or bulging annulus on a nerve root. Impairment caused by such abnormalities usually

improves with time or responds to treatment. Appropriate abnormal physical findings must be shown to persist on repeated examinations despite therapy for a reasonable presumption to be made that severe impairment will last for a continuous period of 12 months. This may occur in cases with unsuccessful prior surgical treatment.

Evaluation of the impairment caused by disorders of the spine requires that a clinical diagnosis of the entity to be evaluated first must be established on the basis of adequate history, physical examination, and roentgenograms. The specific findings stated in 1.05C represent the level required for that impairment; these findings, by themselves, are not intended to represent the basis for establishing the clinical diagnosis. Furthermore, while neurological examination findings are required, they are not to be interpreted as a basis for evaluating the magnitude of any neurological impairment. Neurological impairments are to be evaluated under 11.00-11.19.

The history must include a detailed description of the character, location, and radiation of pain; mechanical factors which incite and relieve pain; prescribed treatment, including type, dose, and frequency of analgesic; and typical daily activities. Care must be taken to ascertain that the reported examination findings are consistent with the individual's daily activities.

There must be a detailed description of the orthopedic and neurologic examination findings. The findings should include a description of gait, limitation of movement of the spine given quantitatively in degrees from the vertical position, motor and sensory abnormalities, muscle spasm, and deep tendon reflexes. Observations of the individual during the examination should be reported; e.g., how he or she gets on and off the examining table. Inability to walk on heels or toes, to squat, or to arise from a squatting position, where appropriate, may be considered evidence of significant motor loss. However, a report of atrophy is not acceptable as evidence of significant motor loss without circumferential measurements of both thighs and lower legs (or upper or lower arms) at a stated point above and below the knee or elbow given in inches or centimeters. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip strength.

These physical examination findings must be determined on the basis of objective observations during the examination and not simply a report of the individual's allegation, e.g., he says his leg is weak, numb, etc. Alternative testing methods should be used to verify the objectivity of the abnormal findings, e.g., a seated straight-leg raising test in addition to a supine straight-leg raising test. Since abnormal findings may be intermittent, their continuous presence over a period of time must be established by a record of ongoing treatment. Neurological abnormalities may not completely subside after surgical or nonsurgical treatment, or with the passage of time. Residual neurological abnormalities, which persist after it has been determined clinically or by direct surgical or other observation that the ongoing or progressive condition is no longer present, cannot be considered to satisfy the required findings in 1.05C.

Where surgical procedures have been performed, documentation should include a

copy of the operative note and available pathology reports.

Electrodiagnostic procedures and myelography may be useful in establishing the clinical diagnosis, but do not constitute alternative criteria to the requirements in 1.05C.

C. After maximum benefit from surgical therapy has been achieved in situations involving fractures of an upper extremity (see 1.12) or soft tissue injuries of a lower or upper extremity (see 1.13), i.e., there have been no significant changes in physical findings or X-ray findings for any 6-month period after the last definitive surgical procedure, evaluation should be made on the basis of demonstrable residuals.

D. Major joints as used herein refer to hip, knee, ankle, shoulder, elbow, or wrist and hand. (Wrist and hand are considered together as one major joint.)

Part B

Medical criteria for the evaluation of impairments of children under age 18 (where criteria in Part A do not give appropriate consideration to the particular disease process in childhood).

Sec.

- 100.00 Growth Impairment.
- 101.00 Musculoskeletal System.
- 102.00 Special Senses and Speech.
- 103.00 Respiratory System.
- 104.00 Cardiovascular System.
- 105.00 Digestive System.
- 106.00 Genito-Urinary System.
- 107.00 Hemio and Lymphatic System.
- 108.00 [Reserved]
- 109.00 Endocrine System.
- 110.00 Multiple Body Systems.
- 111.00 Neurological.
- 112.00 Mental and Emotional Disorders.
- 113.00 Neoplastic Diseases, Malignant.
- 114.00 Immune System.

100.00 GROWTH IMPAIRMENT

A. Impairment of growth may be disabling in itself or it may be an indicator of the severity of the impairment due to a specific disease process.

Determinations of growth impairment should be based upon the comparison of current height with at least three previous determinations, including length at birth, if available. Heights (or lengths) should be plotted on a standard growth chart, such as derived from the National Center for Health Statistics: NCHS Growth Charts. Height should be measured without shoes. Body weight corresponding to the ages represented by the heights should be furnished. The adult heights of the child's natural parents and the heights and ages of siblings should also be furnished. This will provide a basis upon which to identify those children whose short stature represents a familial characteristic rather than a result of disease. This is particularly true for adjudication under 100.02B.

B. Bone age determinations should include a full descriptive report of roentgenograms specifically obtained to determine bone age and must cite the standardization method used. Where roentgenograms must be obtained currently as a basis for adjudication under 100.03, views of the left hand and wrist should be ordered. In addition, roentgenograms of the knee and ankle should be obtained when cessation of growth is being evaluated in an older child at, or past, puberty.

C. The criteria in this section are applicable until closure of the major epiphyses. The cessation of significant increase in height at that point would prevent the application of these criteria.

100.01 Category of Impairments, Growth.

100.02 Growth impairment, considered to be related to an additional specific medically determinable impairment, and one of the following:

A. Fall of greater than 15 percentiles in height which is sustained; or

B. Fall to, or persistence of, height below the third percentile.

100.03 Growth impairment, not identified as being related to an additional, specific medically determinable impairment. With:

A. Fall of greater than 25 percentiles in

height which is sustained; and

B. Bone age greater than two standard deviations (2 SD) below the mean for chronological age (see 100.00B).

101.00 MUSCULOSKELETAL SYSTEM

A. Rheumatoid arthritis. Documentation of the diagnosis of juvenile rheumatoid arthritis should be made according to an established protocol, such as that published by the Arthritis Foundation, *Bulletin on the Rheumatic Diseases*, Vol. 23, 1972-1973 Series, p. 712. Inflammatory signs include persistent pain, tenderness, erythema, swelling, and increased local temperature of a joint.

B. The measurements of joint motion are based on the technique for measurements described in the "Joint Method of Measuring and Recording," published by the American Academy of Orthopedic Surgeons in 1965, or "The Extremities and Back" in *Guides to the Evaluation of Permanent Impairment*, Chicago, American Medical Association, 1971, Chapter 1, pp. 1-48.

C. Degenerative arthritis may be the end stage of many skeletal diseases and conditions, such as traumatic arthritis, collagen disorders, septic arthritis, congenital dislocation of the hip, aseptic necrosis of the hip, slipped capital femoral epiphyses, skeletal dysplasia, etc.

101.01 Category of Impairments, Musculoskeletal

101.02 Juvenile rheumatoid arthritis. With:

A. Persistence or recurrence of joint inflammation despite three months of medical treatment and one of the following:

1. Limitation of motion of two major joints of 50 percent or greater; or
2. Fixed deformity of two major weight-bearing joints of 30 degrees or more; or
3. Radiographic changes of joint narrowing, erosion, or subluxation; or
4. Persistent or recurrent systemic involvement, such as iridocyclitis or pericarditis; or

B. Steroid dependence.

101.03 Deficit of musculoskeletal function due to deformity or musculoskeletal disease and one of the following:

- A. Walking is markedly reduced in speed or distance despite orthotic or prosthetic devices; or
- B. Ambulation is possible only with obligatory bilateral upper limb assistance (e.g., with walker, crutches); or
- C. Inability to perform age-related personal self-care activities involving feeding, dressing, and personal hygiene.

101.05 Disorders of the spine

A. Fracture of vertebra with cord involvement (substantiated by appropriate sensory and motor loss); or

B. Scoliosis (congenital idiopathic or neuromyopathic). With:

1. Major spinal curve measuring 60 degrees or greater; or
2. Spinal fusion of six or more levels. Consider under a disability for one year from the time of surgery; thereafter evaluate the residual impairment; or
3. FEV (vital capacity) of 50 percent or less of predicted normal values for the individual's measured (actual) height; or
4. Kyphosis or lordosis measuring 90 degrees or greater.

101.08 Chronic osteomyelitis with persistence or recurrence of inflammatory signs or drainage for at least 6 months despite prescribed therapy and consistent radiographic findings.

102.00 SPECIAL SENSES AND SPEECH

A. Visual impairments in children. Impairment of central visual acuity should be determined with use of the standard Snellen chart. Where this cannot be used, as in very young children, a complete description should be provided of the findings using other appropriate methods of examination, including a description of the techniques used for determining the central visual acuity for distance.

The accommodative reflex is generally not present in children under 6 months of age. In premature infants, it may not be present until 6 months plus the number of months the child is premature. Therefore absence of accommodative reflex will be considered as

indicating a visual impairment only in children above this age (8 months).

Documentation of a visual disorder must include description of the ocular pathology.

B. Hearing impairments in children. The criteria for hearing impairments in children take into account that a lesser impairment in hearing which occurs at an early age may result in a severe speech and language disorder.

Improvement by a hearing aid, as predicted by the testing procedure, must be demonstrated to be feasible in that child, since younger children may be unable to use a hearing aid effectively.

The type of audiometric testing performed must be described and a copy of the results must be included. The pure tone air conduction hearing levels in 102.08 are based on American National Standard Institute Specifications for Audiometers, S3.6-1969 (ANSI-1969). The report should indicate the specifications used to calibrate the audiometer.

The finding of a severe impairment will be based on the average hearing levels at 500, 1000, 2000, and 3000 Hertz (Hz) in the better ear, and on speech discrimination, as specified in §102.08.

102.01 Category of Impairments, Special Sense Organs

102.02 *Impairments of central visual acuity.*

A. Remaining vision in the better eye after best correction is 20/200 or less; or

B. For children below 3 years of age at time of adjudication:

1. Absence of accommodative reflex (see 102.00A for exclusion of children under 6 months of age); or

2. Retrolental fibroplasia with macular scarring or neovascularization; or

3. Bilateral congenital cataracts with visualization of retinal red reflex only or when associated with other ocular pathology.

102.08 *Hearing impairments.*

A. For children below 5 years of age at time of adjudication, inability to hear air conduction thresholds at an average of 40 decibels (db) hearing level or greater in the better ear; or

B. For children 5 years of age and above at time of adjudication:

1. Inability to hear air conduction thresholds at an average of 70 decibels (db) or greater in the better ear; or

2. Speech discrimination scores at 40 percent or less in the better ear; or

3. Inability to hear air conduction thresholds at an average of 40 decibels (db) or greater in the better ear, and a speech and language disorder which significantly affects the clarity and content of the speech and is attributable to the hearing impairment.

103.00 RESPIRATORY SYSTEM

A. Introduction. The listings in this section describe impairments resulting from respiratory disorder based on symptoms, phys-

ical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders, along with any associated impairment(s) must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment. Reasonable efforts should be made to ensure evaluation by a program physician specializing in childhood respiratory impairments or a qualified pediatrician.

Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is such evidence, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response because this medical management may have improved the child's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some children will not have received ongoing treatment or have an ongoing relationship with the medical community, despite the existence of a severe impairment(s). A child who does not receive treatment may or may not be able to show an impairment that meets the criteria of these listings. Even if a child does not show that his or her impairment meets the criteria of these listings, the child may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a substantial reduction in the ability to function independently, appropriately, and effectively in an age-appropriate manner. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the child's functioning, and the frequency, severity, and duration of symptoms. Also, the asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Evaluation should include consideration of adverse effects of respiratory impairment in all relevant body systems, and especially on the child's growth and development or mental functioning, as described under the growth impairment (100.00), neurological (111.00), and mental disorders (112.00) listings.

It must be remembered that these listings are only examples of common respiratory disorders that are severe enough to prevent a child from functioning independently, appropriately, and effectively in an age-appropriate manner. When a child has a medically determinable impairment that is not listed, an impairment which does not meet a list-

ing, or a combination of impairments no one of which meets a listing, we may make an equivalence determination on medical or functional grounds. Also, with respect to children claiming SSI benefits under title XVI of the Act who have an impairment(s) with a level of severity which does not meet or equal (medically or functionally) the criteria of the listings, we will determine whether the impairment(s) is of comparable severity to one that would disable an adult. In these cases, we will perform an individualized functional assessment to determine whether the child is disabled.

B. Documentation of Pulmonary Function Testing. The results of spirometry that are used for adjudication, under the 103.02 A and B, 103.03, and 103.04 of these listings should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV₁) and forced vital capacity (FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory spiograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV₁ and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment. Peak flow should be achieved early in expiration, and the spiogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV₁ and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spiogram is satisfactory for measurement of the FEV₁ if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spiogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV₁ value is less than the appropriate reference value in table I or III, as appropriate. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the child is not having an asthmatic attack or suffering from an acute respiratory infection or other chronic illness). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and

does not preclude testing. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents a child from performing age-appropriate activities, unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in 103.02 and 103.04 must only be used as criteria for the level of ventilatory impairment that exists during the child's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the child's name, date of testing, distance per second on the abscissa and distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and record the spiogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spiogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the spirometric tracing must show a recorded calibration of volume units using a mechanical volume input such as a 3 L syringe.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min (3 L/6 sec), 60 L/min (3 L/3 sec), and 180 L/min (3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the flow sensor to the child should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the child's actual spiograms.

The spiogram must be recorded at a speed of at least 20 mm/sec and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV₁ from a flow volume tracing is not acceptable, i.e., the spiogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the child's ability to understand directions, as well as

his or her efforts and cooperation in performing the pulmonary function tests.

Purchase of a pulmonary function test is appropriate only when the child is capable of performing reproducible forced expiratory maneuvers. This capability usually occurs around age 6. Purchase of a pulmonary function test may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The pulmonary function tables in 103.02 and 103.04 are based on measurement of standing height without shoes. If a child has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

C. Documentation of chronic impairment of gas exchange.

1. *Arterial blood gas studies (ABGS).* An ABGS performed at rest (while breathing room air, awake and sitting or standing) should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of children with pulmonary disease, must review the clinical and laboratory data short of this procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the child.

2. *Oximetry.* Pulse oximetry may be substituted for arterial blood gases in children under 12 years of age. The oximetry unit should employ the basic technology of spectrophotometric plethysmography as described in Taylor, M.B., and Whitwain, J.G., "Current Status of Pulse Oximetry," "Anesthesia," Vol. 41, No. 9, pp. 943-949, 1986. The unit should provide a visual display of the pulse signal and the corresponding oxygen saturation. A hard copy of the readings (heart rate and saturation) should be provided. Readings should be obtained for a minimum of 5 minutes. The written report should describe patient activity during the recording, i.e., sleep rate, feeding, or exercise. Correlation between the actual heart rate determined by a trained observer and that displayed by the oximeter should be provided. A statement should be made in the

report of the child's effort and cooperation during the test.

Purchase of oximetry may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and may impact on a child's growth and development. It is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis," published by the Cystic Fibrosis Foundation and contained in, "A Test for Concentration of Electrolytes in Sweat in Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, I.E., and Cooke, R.E., "Pediatrics," Vol 23: 545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 103.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the listings for the digestive system (105.00) or growth impairments (100.00). Because cystic fibrosis may involve the respiratory and digestive body systems, as well as impact on a child's growth and development, the combined effects of this involvement must be considered in case adjudication.

E. *Bronchopulmonary dysplasia (BPD).* Bronchopulmonary dysplasia is a form of chronic obstructive pulmonary disease that arises as a consequence of acute lung injury in the newborn period and treatment of hyaline membrane disease, meconium aspiration, neonatal pneumonia and apnea of prematurity. The diagnosis is established by the requirement for continuous or nocturnal supplemental oxygen for more than 30 days, in association with characteristic radiographic changes and clinical signs of respiratory dysfunction, including retractions, rales, wheezing, and tachypnea.

103.01 Category of Impairments, Respiratory System

103.02 *Chronic pulmonary insufficiency.*
With:

A. Chronic obstructive pulmonary disease, due to any cause, with the FEV₁ equal to or less than the value specified in Table I corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

TABLE I

Height without shoes (centimeters)	Height without shoes (inches)	FEV ₁ equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120-129	47-50	0.75
130-139	51-54	0.95
140-149	55-58	1.15
150-159	59-62	1.35
160-164	63-64	1.45
165-169	65-66	1.55
170 or more	67 or more	1.65

Or

B. Chronic restrictive ventilatory disease, due to any cause, with the FVC equal to or less than the value specified in table II corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

TABLE II

Height without shoes (centimeters)	Height without shoes (inches)	FVC equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120-129	47-50	0.85
130-139	51-54	1.05
140-149	55-58	1.25
150-159	59-62	1.45
160-164	63-64	1.65
165-169	65-66	1.75
170 or more	67 or more	2.05

Or

C Frequent need for:

1. Mechanical ventilation; or

2. Nocturnal supplemental oxygen as required by persistent or recurrent episodes of hypoxemia;

Or

D. The presence of a tracheostomy in a child under 3 years of age;

Or

E. Bronchopulmonary dysplasia characterized by two of the following:

1. Prolonged expirations; or

2. Intermittent wheezing or increased respiratory effort as evidenced by retractions, flaring and tachypnea; or

3. Hyperinflation and scarring on a chest radiograph or other appropriate imaging techniques; or

4. Bronchodilator or diuretic dependency;

or

5. A frequent requirement for nocturnal supplemental oxygen; or

6. Weight disturbance with:

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

F. Two required hospital admissions (each longer than 24 hours) within a 6-month period for recurrent lower respiratory tract infections or acute respiratory distress associated with:

1. Chronic wheezing or chronic respiratory distress; or

2. Weight disturbance with:

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

G. Chronic hypoventilation (PaCO₂ greater than 45 mm Hg) or chronic cor pulmonale as described under the appropriate criteria in 104.02;

Or

H. Growth impairment as described under the criteria in 100.00.

103.03 Asthma. With:

A. FEV₁ equal to or less than the value specified in Table I of 103.02A;

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks;

Or

C. Persistent low-grade wheezing between acute attacks or absence of extended symptom-free periods requiring daytime and nocturnal use of sympathomimetic bronchodilators with one of the following:

1. Persistent prolonged expiration with radiographic or other appropriate imaging techniques evidence of pulmonary hyperinflation or peribronchial disease; or

2. Short courses of corticosteroids that average more than 5 days per month for at least 3 months during a 12-month period;

Or

D. Growth Impairment as described under the criteria in 100.00.

103.04 Cystic fibrosis. With:

A. An FEV₁ equal to or less than the appropriate value specified in Table III corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

Or

B. For children in whom pulmonary function testing cannot be performed, the presence of two of the following:

1. History of dyspnea on exertion or accumulation of secretions as manifested by repetitive coughing or cyanosis; or

2. Persistent bilateral rales and rhonchi or substantial reduction of breath sounds related to mucous plugging of the trachea or bronchi; or

3. Radiographic evidence of extensive disease, such as thickening of the proximal bronchial airways or persistence of bilateral peribronchial infiltrates;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial treatment;

Or

D. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

E. Growth Impairment as described under the criteria in 100.00.

TABLE III

[Applicable only for evaluation under 103.04A—cystic fibrosis]

Height without shoes (centimeters)	Height without shoes (inches)	FEV ₁ equal to or less than (L. BTPS)
119 or less	46 or less	0.75
120-129	47-50	0.85
130-139	51-54	1.05

TABLE III—Continued

[Applicable only for evaluation under 103.04A—cystic fibrosis]

Height without shoes (centimeters)	Height without shoes (inches)	FEV ₁ equal to or less than (L. BTPS)
140-149	55-58	1.35
150-159	59-62	1.55
160-164	63-64	1.85
165-169	65-66	2.05
170 or more	67 or more	2.25

104.00 CARDIOVASCULAR SYSTEM

A. Introduction

The listings in this section describe childhood impairments resulting from congenital or acquired cardiovascular disease based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of therapy prescribed by a treating source. A longitudinal clinical record covering a period of not less than 3 months of observations and therapy is usually necessary for the assessment of severity and expected duration unless the child is a neonate or the claim can be decided favorably on the basis of the current evidence. All relevant evidence must be considered in assessing a child's disability. Reasonable efforts should be made to ensure evaluation by a program physician specializing in childhood cardiovascular impairments or a qualified pediatrician.

Examples of congenital defects include: abnormalities of cardiac septation, such as ventricular septal defect or atrioventricular (AV) canal; abnormalities resulting in cyanotic heart disease, such as tetralogy of Fallot or transposition of the vessels; valvular defects or obstructions to ventricular outflow, including pulmonary or aortic stenosis and/or coarctation of the aorta; and major abnormalities of ventricular development, including hypoplastic left heart syndrome or pulmonary tricuspid atresia with hypoplastic right ventricle. Acquired heart disease may be due to cardiomyopathy, rheumatic heart disease, Kawasaki syndrome, or other etiologies. Recurrent arrhythmias, severe enough to cause functional impairment, may be seen with congenital or acquired heart disease or, more rarely, in children with structurally normal hearts.

Cardiovascular impairments, especially chronic heart failure and congenital heart disease, may result in impairments in other body systems including, but not limited to, growth, neurological, and mental. Therefore, evaluation should include consideration of the adverse effects of cardiovascular impairment in all relevant body systems, and especially on the child's growth and development, or mental functioning, as described under the Growth Impairment (100.00). Neu-

rological (111.00), and Mental retardation (112.05) listings.

Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the therapy prescribed by the treating source and response. In addition to information about the nature and severity of the impairment. It is important to document any prescribed therapy and response because this medical management may have improved the child's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some children will not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the child's functioning, and the frequency, severity, and duration of symptoms. Also, several listings include a requirement for continuing signs and symptoms despite a regimen of prescribed treatment. Even though a child who does not receive treatment may not be able to show an impairment that meets the criteria of these listings, the child may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a substantial reduction in the ability to function independently, appropriately, and effectively in an age-appropriate manner.

Indeed, it must be remembered that these listings are only examples of common cardiovascular disorders that are severe enough to prevent a child from functioning independently, appropriately, and effectively in an age-appropriate manner. When a child has a medically determinable impairment that is not listed, or a combination of impairments no one of which meets a listing, we will make an equivalence determination. Also, with respect to children claiming SSI benefits under title XVI of the Act who have an impairment(s) with a level of severity which does not meet or equal the criteria of the cardiovascular listings, we will determine whether the impairment(s) is of comparable severity to one that would disable an adult. In these cases, an individualized functional assessment is crucial to the evaluation of a child's ability to function independently, appropriately, and effectively in an age-appropriate manner when the impairment(s) is severe but the criteria of these listings are not met or equaled.

B. Documentation

Each child's file must include sufficiently detailed reports on history, physical examinations, laboratory studies, and any prescribed therapy and response to allow an independent reviewer to assess the severity and duration of the cardiovascular impairment. Data should be obtained preferably from an office or center experienced in pediatric cardiac assessment. The actual electrocardiographic tracing (or adequately marked photocopy) and echocardiogram report with a copy of relevant echocardiographic views should be included (see part A, 4.00C1).

Results of additional studies necessary to substantiate the diagnosis or to document the severity of the impairment, including two-dimensional and Doppler echocardiography, and radionuclide ventriculograms, should be obtained as appropriate according to part A, 4.00C3. Ambulatory electrocardiographic monitoring may also be obtained if necessary to document the presence or severity of an arrhythmia.

Exercise testing, though increasingly used, is still less frequently indicated in children than in adults, and can rarely be successfully performed in children under 6 years of age. It may be of value in the assessment of some arrhythmias, in the assessment of the severity of chronic heart failure, and in the assessment of recovery of function following cardiac surgery or other therapy. It will only be purchased by the Social Security Administration if the case cannot be decided based on the available evidence and, if purchased, must be performed in a specialty center for pediatric cardiology or other facility qualified to perform exercise testing for children.

Purchased exercise tests should be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. An exercise test should not be purchased for a child for whom the performance of the test is considered to constitute a significant risk by a program physician. See 4.00C2c.

Cardiac catheterization will not be purchased by the Social Security Administration. If the results of catheterization are otherwise available, they should be obtained.

C. Treatment and Relationship to Functional Status

In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The overall clinical and laboratory evidence, including the treatment plan(s) or results, should be persuasive that a listing-level impairment exists. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with

the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, impairment evaluation may need to be deferred for a period of up to 3 months from the date of treatment to permit consideration of treatment effects.

Evaluation should not be deferred if the claim can be favorably decided based upon the available evidence.

The most life-threatening forms of congenital heart disease and cardiac impairments, such as those listed in 104.00D, almost always require surgical treatment within the first year of life to prevent early death. Even with surgery, these impairments are so severe that it is likely that the impairment will continue to be disabling long enough to meet the duration requirement because of significant residual impairment post-surgery, or the recovery time from surgery, or a combination of both factors. Therefore, when the impairment is one of those named in 104.00D, or is as severe as one of those impairments, the presence of a listing-level impairment can usually be found on the basis of planned or actual cardiac surgery.

A child who has undergone surgical treatment for life-threatening heart disease will be found under a disability for 12 months following the date of surgery under 104.06H (for infants with life-threatening cardiac disease) or 104.09 (for a child of any age who undergoes cardiac transplantation) because of the uncertainty during that period concerning outcome or long-term results. After 12 months, continuing disability evaluation will be based upon residual impairment, which will consider the clinical course following treatment and comparison of symptoms, signs, and laboratory findings preoperatively and after the specified period. (See §§416.994a, 404.1594, or 416.994, as appropriate, for our rules on medical improvement and whether an individual is no longer disabled.)

D. Congenital Heart Disease

Some congenital defects usually lead to listing-level impairment in the first year of life and require surgery within the first year as a life-saving measure. Examples of impairments that in most instances will require life-saving surgery before age 1, include, but are not limited to, the following: hypoplastic left heart syndrome; critical aortic stenosis with neonatal heart failure; critical coarctation of the aorta, with or without associated anomalies; complete AV canal defects; transposition of the great arteries; tetralogy of Fallot; and pulmonary atresia with intact ventricular septum.

In addition, there are rarer defects which may lead to early mortality and that may require multiple surgical interventions or a combination of surgery and other major

interventional procedures (e.g., multiple "balloon" catheter procedures). Examples of such defects include single ventricle, tricuspid atresia, and multiple ventricular septal defects.

Pulmonary vascular obstructive disease can cause cardiac impairment in young children. When a large or nonrestrictive septal defect or ductus is present, pulmonary artery mean pressures of at least 70 percent of mean systemic levels are used as a criterion of listing-level impairment. In the absence of such a defect (i.e., with primary pulmonary hypertension, or in some connective tissue disorders with cardiopulmonary involvement and pulmonary vascular destruction), listing-level impairment may be present at lower levels of pulmonary artery pressure, in the range of at least 50 percent of mean systemic levels.

E. Chronic Heart Failure

Chronic heart failure in infants and children may manifest itself by pulmonary or systemic venous congestion, including cardiomegaly, chronic dyspnea, tachypnea, orthopnea, or hepatomegaly; or symptoms of limited cardiac output, such as weakness or fatigue; or a need for cardiotonic drugs. Fatigue or exercise intolerance in an infant may be manifested by prolonged feeding time associated with signs of cardiac impairment, including excessive respiratory effort and sweating. Other manifestations of chronic heart failure during infancy may include failure to gain weight or involuntary loss of weight and repeated lower respiratory tract infections.

Cardiomegaly or ventricular dysfunction must be present and demonstrated by imaging techniques, such as two-dimensional and Doppler echocardiography. (Reference: Feigenbaum, Harvey, "Echocardiography," 4th Edition, Lea and Febiger, 1986, Appendix, pp. 621-639.) Chest x-ray (6 ft. PA film) will be considered indicative of cardiomegaly if the cardiothoracic ratio is over 60 percent at age 1 year or less, or 55 percent at more than 1 year of age.

Findings of cardiomegaly on chest x-ray must be accompanied by other evidence of chronic heart failure or ventricular dysfunction. This evidence may include clinical evidence, such as hepatomegaly, edema, or pulmonary venous congestion; or echocardiographic evidence, such as marked ventricular dilatation above established normals for age, or markedly reduced ejection fraction or shortening fraction.

F. Valvular Heart Disease

Valvular heart disease requires documentation by appropriate imaging techniques, including Doppler echocardiogram studies or cardiac catheterization if catheterization results are available from a

treating source or other source of record. Listing-level impairment is usually associated with critical aortic stenosis in a newborn child, persistent heart failure, arrhythmias, or valve replacement and ongoing anticoagulant therapy. The usual time after valvular surgery for adequate assessment of the results of treatment is considered to be 3 months.

G. Rheumatic Heart Disease

The diagnosis should be made in accordance with the current revised Jones criteria for guidance in the diagnosis of rheumatic fever.

104.01 *Category of Impairments, Cardiovascular System*

104.02 *Chronic heart failure.* Documented by clinical and laboratory findings as described in 104.00E, and with one of the following:

A. Persistent tachycardia at rest (see Table I);

OR

B. Persistent tachypnea at rest (see Table II), or markedly decreased exercise tolerance (see 104.00E);

OR

C. Recurrent arrhythmias, as described in 104.05;

OR

D. Growth disturbance, with:

1. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

2. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer; or

3. Growth impairment as described under the criteria in 100.00.

TABLE I—TACHYCARDIA AT REST

Age	Apical heart (beats per minute)
Under 1 yr	150
1 through 3 yrs	130
4 through 9 yrs	120
10 through 15 yrs	110
Over 15 yrs	100

TABLE II—TACHYPNEA AT REST

Age	Respiratory rate over (per minute)
Under 1 yr	40
1 through 5 yrs	35
6 through 9 yrs	30
Over 9 yrs	25

104.03 *Hypertensive cardiovascular disease.* With persistently elevated blood pressure equal to or greater than the 95th percentile for age (see Table III), and one of the following:

A. Impaired renal function, as described in 106.02;

OR

B. Cerebrovascular damage, as described in 111.06;

OR

C. Chronic heart failure as described in 104.02.

TABLE III—ELEVATED BLOOD PRESSURE

Age	Systolic over (mmHg)	OR	Diastolic over (mmHg)
Under 1 month	95		—
1 month through 2 yrs	112		74
3 through 5 yrs	116		76
6 through 9 yrs	122		78
10 through 12 yrs	126		82
13 through 15 yrs	136		86
16 to 18 yrs	142		92

104.05 *Recurrent arrhythmias,* such as persistent or recurrent heart block (A-V dissociation), repeated symptomatic tachyarrhythmias or bradyarrhythmias or long QT syndrome arrhythmias, not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in

uncontrolled repeated episodes of cardiac syncope or near syncope and arrhythmia despite prescribed treatment, including electronic pacemaker (see 104.00A if there is no prescribed treatment), and documented by resting or ambulatory (Holter) electrocardiography coincident with the occurrence of syncope or near syncope.

104.06 *Congenital heart disease*. With one of the following:

A. Cyanotic heart disease, with persistent, chronic hypoxemia as manifested by:

1. Hematocrit of 55 percent or greater on two or more evaluations within a 3-month period; or

2. Arterial O₂ saturation of less than 90 percent in room air, or resting PO₂ of 60 Torr or less; or

3. Hypercyanotic spells, syncope, characteristic squatting, or other incapacitating symptoms directly related to documented cyanotic heart disease; or

4. Exercise intolerance with increased hypoxemia on exertion;

OR

B. Chronic heart failure with evidence of ventricular dysfunction, as described in 104.02;

OR

C. Recurrent arrhythmias as described in 104.05;

OR

D. Secondary pulmonary vascular obstructive disease with a mean pulmonary arterial pressure elevated to at least 70 percent of the mean systemic arterial pressure;

OR

E. Congenital valvular or other stenotic defects, or valvular regurgitation, as described in 104.00F and 104.07;

OR

F. Symptomatic acyanotic heart disease, with ventricular dysfunction resulting in significant restriction of age-appropriate activities or inability to complete age-appropriate tasks (see 104.00A);

OR

G. Growth failure, as described in 100.00;

OR

H. For infants under 12 months of age at the time of filing, with life-threatening congenital heart impairment that will or has required surgical treatment in the first year of life, consider the infant to be under a disability until the attainment of age 1 or for 12 months after surgery, whichever is the later event; thereafter, evaluate impairment severity with reference to 104.02 to 104.08.

104.07 *Valvular heart disease or other stenotic defects, or valvular regurgitation*, documented by appropriate imaging techniques or cardiac catheterization.

A. Evaluate according to criteria in 104.02, 104.05, 111.06, or 111.04;

OR

B. Critical aortic stenosis in newborn.

104.08 *Cardiomyopathies*, documented by appropriate imaging techniques, including echocardiography or cardiac catheterization, if catheterization results are available from a treating source. Impairment must be associated with an ejection fraction of 50 percent or less and significant left ventricular dilatation using standardized age-appropriate echocardiographic ventricular cavity meas-

urements. Evaluate under the criteria in 104.02, 104.05, or 111.06.

104.09 *Cardiac transplantation*. Consider under a disability for 1 year following surgery; thereafter, evaluate residual impairment under 104.02 to 104.08.

104.13 *Chronic rheumatic fever or rheumatic heart disease*. Consider under a disability for 18 months from the established onset of impairment with one of the following:

A. Persistence of rheumatic fever activity for 6 months or more which is manifested by significant murmur(s), cardiac enlargement (see 104.00E) or ventricular dysfunction, and other abnormal laboratory findings, as for example, an elevated sedimentation rate or ECG findings;

OR

B. Evidence of chronic heart failure, as described under 104.02;

OR

C. Recurrent arrhythmias, as described under 104.05.

104.14 *Hyperlipidemia*. Documented Type II homozygous hyperlipidemia with repeated plasma cholesterol levels of 500 mg/ml or greater, with one of the following:

A. Myocardial ischemia, as described in 4.04B or 4.04C;

OR

B. Significant aortic stenosis documented by Doppler echocardiographic techniques or cardiac catheterization;

OR

C. Major disruption of normal life activities by repeated hospitalizations for plasmapheresis or other prescribed therapies, including liver transplant;

OR

D. Recurrent pancreatitis complicating hyperlipidemia.

104.15 *Kawasaki syndrome*. With one of the following:

A. Major coronary artery aneurysm;

OR

B. Chronic heart failure, as described in 104.02.

105.00 DIGESTIVE SYSTEM

A. *Disorders of the digestive system* which result in disability usually do so because of interference with nutrition and growth, multiple recurrent inflammatory lesions, or other complications of the disease. Such lesions or complications usually respond to treatment. To constitute a listed impairment, these must be shown to have persisted or be expected to persist despite prescribed therapy for a continuous period of at least 12 months.

B. *Documentation of gastrointestinal impairments* should include pertinent operative findings, radiographic studies, endoscopy, and biopsy reports. Where a liver biopsy has been performed in chronic liver disease, documentation should include the report of the biopsy.

C. Growth retardation and malnutrition. When the primary disorder of the digestive tract has been documented, evaluate resultant malnutrition under the criteria described in 105.08. Evaluate resultant growth impairment under the criteria described in 100.03. Intestinal disorders, including surgical diversions and potentially correctable congenital lesions, do not represent a severe impairment if the individual is able to maintain adequate nutrition growth and development.

D. Multiple congenital anomalies. See related criteria, and consider as a combination of impairments.

105.01 Category of Impairments, Digestive.

105.03 Esophageal obstruction, caused by atresia, stricture, or stenosis with malnutrition as described under the criteria in 105.08.

105.05 Chronic liver disease. With one of the following:

A. Inoperable biliary atresia demonstrated by X-ray or surgery; or

B. Intractable ascites not attributable to other causes, with serum albumin of 3.0 gm./100 ml. or less; or

C. Esophageal varices (demonstrated by angiography, barium swallow, or endoscopy or by prior performance of a specific shunt or plication procedure); or

D. Hepatic coma, documented by findings from hospital records; or

E. Hepatic encephalopathy. Evaluate under the criteria in 112.02; or

F. Chronic active inflammation or necrosis documented by SGOT persistently more than 100 units or serum bilirubin of 2.5 mg. percent or greater.

105.07 Chronic inflammatory bowel disease (such as ulcerative colitis, regional enteritis), as documented in 105.00. With one of the following:

A. Intestinal manifestations or complications, such as obstruction, abscess, or fistula formation which has lasted or is expected to last 12 months; or

B. Malnutrition as described under the criteria in 105.08; or

C. Growth impairment as described under the criteria in 100.03.

105.08 Malnutrition, due to demonstrable gastrointestinal disease causing either a fall of 15 percentiles of weight which persists or the persistence of weight which is less than the third percentile (on standard growth charts). And one of the following:

A. Stool fat excretion per 24 hours:

1. More than 15 percent in infants less than 6 months.

2. More than 10 percent in infants 6-18 months.

3. More than 6 percent in children more than 18 months; or

B. Persistent hematocrit of 30 percent or less despite prescribed therapy; or

C. Serum carotene of 40 mcg./100 ml. or less; or

D. Serum albumin of 3.0 gm./100 ml. or less.

106.00 GENITO-URINARY SYSTEM

A. Determination of the presence of chronic renal disease will be based upon the following factors:

1. History, physical examination, and laboratory evidence of renal disease.

2. Indications of its progressive nature or laboratory evidence of deterioration of renal function.

B. Renal transplant. The amount of function restored and the time required to effect improvement depend upon various factors including adequacy of post transplant renal function, incidence of renal infection, occurrence of rejection crisis, presence of systemic complications (anemia, neuropathy, etc.) and side effects of corticosteroid or immuno-suppressive agents. A period of at least 12 months is required for the individual to reach a point of stable medical improvement.

C. Evaluate associated disorders and complications according to the appropriate body system listing.

106.01 Category of Impairments, Genito-Urinary.

106.02 Chronic renal disease. With:

A. Persistent elevation of serum creatinine to 3 mg. per deciliter (100 ml.) or greater over at least 3 months; or

B. Reduction of creatinine clearance to 30 ml. per minute (43 liters/24 hours) per 1.73 m² of body surface area over at least 3 months; or

C. Chronic renal dialysis program for irreversible renal failure; or

D. Renal transplant. Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment (see 106.00B).

106.06 Nephrotic syndrome, with edema not controlled by prescribed therapy. And:

A. Serum albumin less than 2 gm./100 ml.; or

B. Proteinuria more than 2.5 gm./1.73m² day.

107.00 HEMIC AND LYMPHATIC SYSTEM

A. Sickle cell disease. Refers to a chronic hemolytic anemia associated with sickle cell hemoglobin, either homozygous or in combination with thalassemia or with another abnormal hemoglobin (such as C or F).

Appropriate hematologic evidence for sickle cell disease, such as hemoglobin electrophoresis must be included. Vaso-occlusive, hemolytic, or aplastic episodes should be documented by description of severity, frequency, and duration.

Disability due to sickle cell disease may be solely the result of a severe, persistent anemia or may be due to the combination of

chronic progressive or episodic manifestations in the presence of a less severe anemia.

Major visceral episodes causing disability include meningitis, osteomyelitis, pulmonary infections or infarctions, cerebrovascular accidents, congestive heart failure, genitourinary involvement, etc.

B. Coagulation defects. Chronic inherited coagulation disorders must be documented by appropriate laboratory evidence such as abnormal thromboplastin generation, coagulation time, or factor assay.

C. Acute leukemia. Initial diagnosis of acute leukemia must be based upon definitive bone marrow pathologic evidence. Recurrent disease may be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The pathology report must be included.

The designated duration of disability implicit in the finding of a listed impairment is contained in 107.11. Following the designated time period, a documented diagnosis itself is no longer sufficient to establish a severe impairment. The severity of any remaining impairment must be evaluated on the basis of the medical evidence.

107.01 Category of Impairments, Hemis and Lymphatic.

107.03 Hemolytic anemia (due to any cause). Manifested by persistence of hematocrit of 26 percent or less despite prescribed therapy, and reticulocyte count of 4 percent or greater.

107.05 Sickle cell disease. With:

A. Recent, recurrent, severe vaso-occlusive crises (musculoskeletal, vertebral, abdominal); or

B. A major visceral complication in the 12 months prior to application; or

C. A hyperhemolytic or aplastic crisis within 12 months prior to application; or

D. Chronic, severe anemia with persistence of hematocrit of 26 percent or less; or

E. Congestive heart failure, cerebrovascular damage, or emotional disorder as described under the criteria in 104.02, 111.00ff, or 112.00ff.

107.06 Chronic idiopathic thrombocytopenic purpura of childhood with purpura and thrombocytopenia of 40,000 platelets/cu. mm. or less despite prescribed therapy or recurrent upon withdrawal of treatment.

107.08 Inherited coagulation disorder. With:

A. Repeated spontaneous or inappropriate bleeding; or

B. Hemarthrosis with joint deformity.

107.11 Acute leukemia. Consider under a disability:

A. For 2½ years from the time of initial diagnosis; or

B. For 2½ years from the time of recurrence of active disease.

108.00 [RESERVED]

109.00 ENDOCRINE SYSTEM

A. Cause of disability. Disability is caused by a disturbance in the regulation of the secretion or metabolism of one or more hormones which are not adequately controlled by therapy. Such disturbances or abnormalities usually respond to treatment. To constitute a listed impairment these must be shown to have persisted or be expected to persist despite prescribed therapy for a continuous period of at least 12 months.

B. Growth. Normal growth is usually a sensitive indicator of health as well as of adequate therapy in children. Impairment of growth may be disabling in itself or may be an indicator of a severe disorder involving the endocrine system or other body systems. Where involvement of other organ systems has occurred as a result of a primary endocrine disorder, these impairments should be evaluated according to the criteria under the appropriate sections.

C. Documentation. Description of characteristic history, physical findings, and diagnostic laboratory data must be included. Results of laboratory tests will be considered abnormal if outside the normal range or greater than two standard deviations from the mean of the testing laboratory. Reports in the file should contain the information provided by the testing laboratory as to their normal values for that test.

D. Hyperfunction of the adrenal cortex. Evidence of growth retardation must be documented as described in 100.00. Elevated blood or urinary free cortisol levels are not acceptable in lieu of urinary 17-hydroxycorticosteroid excretion for the diagnosis of adrenal cortical hyperfunction.

E. Adrenal cortical insufficiency. Documentation must include persistent low plasma cortisol or low urinary 17-hydroxycorticosteroids or 17-ketogenic steroids and evidence of unresponsiveness to ACTH stimulation.

109.01 Category of Impairments, Endocrine

109.02 Thyroid Disorders.

A. Hyperthyroidism (as documented in 109.00C). With clinical manifestations despite prescribed therapy, and one of the following:

1. Elevated serum thyroxine (T_4) and either elevated free T_4 or resin T_3 uptake; or

2. Elevated thyroid uptake of radiolodine;

or

3. Elevated serum triiodothyronine (T_3).

B. Hypothyroidism. With one of the following, despite prescribed therapy:

1. IQ of 70 or less; or

2. Growth impairment as described under the criteria in 100.02 A and B; or

3. Precocious puberty.

109.03 Hyperparathyroidism (as documented in 109.00C). With:

A. Repeated elevated total or ionized serum calcium; or

B. Elevated serum parathyroid hormone.

109.04 *Hypoparathyroidism* or *Pseudohypoparathyroidism*. With:

A. Severe recurrent tetany or convulsions which are unresponsive to prescribed therapy; or

B. Growth retardation as described under criteria in 100.02 A and B.

109.05 *Diabetes insipidus*, documented by pathologic hypertonic saline or water deprivation test. And one of the following:

A. Intracranial space-occupying lesion, before or after surgery; or

B. Unresponsiveness to Pitressin; or

C. Growth retardation as described under the criteria in 100.02 A and B; or

D. Unresponsive hypothalamic thirst center, with chronic or recurrent hypernatremia; or

E. Decreased visual fields attributable to a pituitary lesion.

109.06 *Hyperfunction of the adrenal cortex* (Primary or secondary). With:

A. Elevated urinary 17-hydroxycorticosteroids (or 17-ketogenic steroids) as documented in 109.00 C and D; and

B. Unresponsiveness to low-dose dexamethasone suppression.

109.07 *Adrenal cortical insufficiency* (as documented in 109.00 C and E) with recent, recurrent episodes of circulatory collapse.

109.08 *Juvenile diabetes mellitus* (as documented in 109.00C) requiring parenteral insulin. And one of the following, despite prescribed therapy:

A. Recent, recurrent hospitalizations with acidosis; or

B. Recent, recurrent episodes of hypoglycemia; or

C. Growth retardation as described under the criteria in 100.02 A or B; or

D. Impaired renal function as described under the criteria in 106.00ff.

109.09 *Iatrogenic hypercorticotid state*.

With chronic glucocorticoid therapy resulting in one of the following:

A. Osteoporosis; or

B. Growth retardation as described under the criteria in 100.02 A or B; or

C. Diabetes mellitus as described under the criteria in 109.08; or

D. Myopathy as described under the criteria in 111.06; or

E. Emotional disorder as described under the criteria in 112.00ff.

109.10 *Pituitary dwarfism* (with documented growth hormone deficiency). And growth impairment as described under the criteria in 100.02B.

109.11 *Adrenogenital syndrome*. With:

A. Recent, recurrent self-losing episodes despite prescribed therapy; or

B. Inadequate replacement therapy manifested by accelerated bone age and virilization, or

C. Growth impairment as described under the criteria in 100.02 A or B.

109.12 *Hypoglycemia* (as documented in 109.00C). With recent, recurrent hypoglycemic episodes producing convulsion or coma.

109.13 *Gonadal Dysgenesis* (Turner's Syndrome), chromosomally proven. Evaluate the resulting impairment under the criteria for the appropriate body system.

110.00 MULTIPLE BODY SYSTEMS

A. This section refers to those life-threatening catastrophic congenital abnormalities and other serious hereditary, congenital, or acquired disorders that usually affect two or more body systems and are expected to:

1. Result in early death or developmental attainment of less than 2 years of age as described in listing 110.08 (e.g., anencephaly or Tay-Sachs); or

2. Produce long-term, if not life-long, significant interference with age-appropriate major daily or personal care activities as described in listings 110.06 and 110.07. (Significant interference with age-appropriate activities is considered to exist where the developmental milestone age did not exceed two-thirds of the chronological age at the time of evaluation and such interference has lasted or could be expected to last at least 12 months.) See 112.00C for a discussion of developmental milestone criteria and evaluation of age-appropriate activities.

Down syndrome (except for mosaic Down syndrome, which is to be evaluated under listing 110.07) established by clinical findings, including the characteristic physical features, and laboratory evidence is considered to meet the requirement of listing 110.06 commencing at birth. Examples of disorders that should be evaluated under listing 110.07 include mosaic Down syndrome and chromosomal abnormalities other than Down syndrome, in which a pattern of multiple impairments (including mental retardation) is known to occur, phenylketonuria (PKU), fetal alcohol syndrome, and severe chronic neonatal infections such as toxoplasmosis, rubella syndrome, cytomegalic inclusion disease, and herpes encephalitis.

B. Documentation must include confirmation of a positive diagnosis by a clinical description of the usual abnormal physical findings associated with the condition and definitive laboratory tests, including chromosomal analysis, where appropriate (e.g., Down syndrome). Medical evidence that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing, at some time prior to evaluation, is acceptable in lieu of a copy of the actual laboratory report.

C. When multiple body system manifestations do not meet one of the established criteria of one of the listings, the combined impairments must be evaluated together to de-

termine if they are equal in severity to a listed impairment.

110.01 Category of Impairments, Multiple Body Systems

110.06 *Down syndrome (excluding mosaic Down syndrome)* established by clinical and laboratory findings, as described in 110.00B. Consider the child disabled from birth.

110.07 *Multiple body dysfunction* due to any confirmed (see 110.00B) hereditary, congenital, or acquired condition with one of the following:

A. Persistent motor dysfunction as a result of hypotonia and/or musculoskeletal weakness, postural reaction deficit, abnormal primitive reflexes, or other neurological impairment as described in 111.00C, and with significant interference with age-appropriate major daily or personal care activities, which in an infant or young child include such activities as head control, swallowing, following, reaching, grasping, turning, sitting, crawling, walking, taking solids, feeding self; or

B. Mental impairment as described under the criteria in 112.05 or 112.12; or

C. Growth impairment as described under the criteria in 100.02A or B; or

D. Significant interference with communication due to speech, hearing, or visual impairments as described under the criteria in 102.00 and 111.09; or

E. Cardiovascular impairments as described under the criteria in 104.00; or

F. Other impairments such as, but not limited to, malnutrition, hypothyroidism, or seizures should be evaluated under the criteria in 105.08, 109.02 or 111.02 and 111.03, or the criteria for the affected body system.

110.08 *Catastrophic congenital abnormalities or disease.* With:

A. A positive diagnosis (such as anencephaly, trisomy D or E, cyclopa, etc.), generally regarded as being incompatible with extrauterine life; or

B. A positive diagnosis (such as cri du chat, Tay-Sachs Disease) wherein attainment of the growth and development level of 2 years is not expected to occur.

111.00 NEUROLOGICAL

A. *Seizure disorder* must be substantiated by at least one detailed description of a typical seizure. Report of recent documentation should include an electroencephalogram and neurological examination. Sleep EEG is preferable, especially with temporal lobe seizures. Frequency of attacks and any associated phenomena should also be substantiated.

Young children may have convulsions in association with febrile illnesses. Proper use of 111.02 and 111.03 requires that a seizure disorder be established. Although this does not exclude consideration of seizures occurring during febrile illnesses, it does require docu-

mentation of seizures during nonfebrile periods.

There is an expected delay in control of seizures when treatment is started, particularly when changes in the treatment regimen are necessary. Therefore, a seizure disorder should not be considered to meet the requirements of 111.02 or 111.03 unless it is shown that seizures have persisted more than three months after prescribed therapy began.

B. *Minor motor seizures.* Classical petit mal seizures must be documented by characteristic EEG pattern, plus information as to age at onset and frequency of clinical seizures. Myoclonic seizures, whether of the typical infantile or Lennox-gastaut variety after infancy, must also be documented by the characteristic EEG pattern plus information as to age at onset and frequency of seizures.

C. *Motor dysfunction.* As described in 111.06, motor dysfunction may be due to any neurological disorder. It may be due to static or progressive conditions involving any area of the nervous system and producing any type of neurological impairment. This may include weakness, spasticity, lack of coordination, ataxia, tremor, athetosis, or sensory loss. Documentation of motor dysfunction must include neurologic findings and description of type of neurologic abnormality (e.g., spasticity, weakness), as well as a description of the child's functional impairment (i.e., what the child is unable to do because of the abnormality). Where a diagnosis has been made, evidence should be included for substantiation of the diagnosis (e.g., blood chemistries and muscle biopsy reports), wherever applicable.

D. *Impairment of communication.* The documentation should include a description of a recent comprehensive evaluation, including all areas of affective and effective communication, performed by a qualified professional.

111.01 Category of Impairment, Neurological

111.02 *Major motor seizure disorder.*

A. *Major motor seizures.* In a child with an established seizure disorder, the occurrence of more than one major motor seizure per month despite at least three months of prescribed treatment. With:

1. Daytime episodes (loss of consciousness and convulsive seizures); or

2. Nocturnal episodes manifesting residuals which interfere with activity during the day.

B. *Major motor seizures.* In a child with an established seizure disorder, the occurrence of a least one major motor seizure in the year prior to application despite at least three months of prescribed treatment. And one of the following:

1. IQ of 70 or less; or

2. Significant interference with communication due to speech, hearing, or visual defect; or

3. Significant emotional disorder; or

4. Where significant adverse effects of medication interfere with major daily activities.

111.03 *Minor motor seizure disorder.* In a child with an established seizure disorder, the occurrence of more than one minor motor seizure per week, with alteration of awareness or loss of consciousness, despite at least three months of prescribed treatment.

111.05 *Brain tumors. A. Malignant gliomas (astrocytoma—Grades III and IV, glioblastoma multiforme), medulloblastoma, ependymoblastoma, primary sarcoma or brain stem gliomas; or*

B. Evaluate other brain tumors under the criteria for the resulting neurological impairment.

111.06 *Motor dysfunction (due to any neurological disorder).* Persistent disorganization or deficit of motor function for age involving two extremities, which (despite prescribed therapy) interferes with age-appropriate major daily activities and results in disruption of:

- A. Fine and gross movements; or
- B. Gait and station.

111.07 *Cerebral palsy. With:*

A. Motor dysfunction meeting the requirements of 111.06 or 101.03; or

B. Less severe motor dysfunction (but more than slight) and one of the following:

1. IQ of 70 or less; or
2. Seizure disorder, with at least one major motor seizure in the year prior to application; or
3. Significant interference with communication due to speech, hearing or visual defect; or
4. Significant emotional disorder.

111.08 *Meningocele (and related disorders).* With one of the following despite prescribed treatment:

A. Motor dysfunction meeting the requirements of §101.03 or §111.06; or

B. Less severe motor dysfunction (but more than slight), and:

1. Urinary or fecal incontinence when inappropriate for age; or
2. IQ of 70 or less; or
- C. Four extremity involvement; or
- D. Noncompensated hydrocephalus producing interference with mental or motor developmental progression.

111.09 *Communication impairment, associated with documented neurological disorder.* And one of the following:

- A. Documented speech deficit which significantly affects the clarity and content of the speech; or
- B. Documented comprehension deficit resulting in ineffective verbal communication for age; or
- C. Impairment of hearing as described under the criteria in 102.08.

112.00 MENTAL DISORDERS

A. *Introduction:* The structure of the mental disorders listings for children under age 18 parallels the structure for the mental disorders listings for adults but is modified to reflect the presentation of mental disorders in children. The listings for mental disorders in children are arranged in 11 diagnostic categories: Organic mental disorders (112.02); schizophrenic, delusional (paranoid), schizoaffective, and other psychotic disorders (112.03); mood disorders (112.04); mental retardation (112.05); anxiety disorders (112.06); somatoform, eating, and tic disorders (112.07); personality disorders (112.08); psychoactive substance dependence disorders (112.09); autistic disorder and other pervasive developmental disorders (112.10); attention deficit hyperactivity disorder (112.11); and developmental and emotional disorders of newborn and younger infants (112.12).

There are significant differences between the listings for adults and the listings for children. There are disorders found in children that have no real analogy in adults; hence, the differences in the diagnostic categories for children. The presentation of mental disorders in children, particularly the very young child, may be subtle and of a character different from the signs and symptoms found in adults. For example, findings such as separation anxiety, failure to mold or bond with the parents, or withdrawal may serve as findings comparable to findings that mark mental disorders in adults. The activities appropriate to children, such as learning, growing, playing, maturing, and school adjustment, are also different from the activities appropriate to the adult and vary widely in the different childhood stages.

Each listing begins with an introductory statement that describes the disorder or disorders addressed by the listing. This is followed (except in listings 112.05 and 112.12) by medical findings (paragraph A criteria), which, if satisfied, lead to an assessment of impairment-related functional limitations (paragraph B criteria). An individual will be found to have a listed impairment when the criteria of both paragraphs A and B of the listed impairment are satisfied.

The purpose of the criteria in paragraph A is to substantiate medically the presence of a particular mental disorder. Specific symptoms and signs under any of the listings 112.02 through 112.12 cannot be considered in isolation from the description of the mental disorder contained at the beginning of each listing category. Impairments should be analyzed or reviewed under the mental category(ies) indicated by the medical findings.

Paragraph A of the listings is a composite of medical findings which are used to substantiate the existence of a disorder and may or may not be appropriate for children at

specific developmental stages. However, a range of medical findings is included in the listings so that no age group is excluded. For example, in listing 112.02A7, emotional lability and crying would be inappropriate criteria to apply to older infants and toddlers, age 1 to attainment of age 3; whereas in 112.02A1, developmental arrest, delay, or regression are appropriate criteria for older infants and toddlers. Whenever the adjudicator decides that the requirements of paragraph A of a particular mental listing are satisfied, then that listing should be applied regardless of the age of the child to be evaluated.

The purpose of the paragraph B criteria is to describe impairment-related functional limitations which are applicable to children. Standardized tests of social or cognitive function and adaptive behavior are frequently available and appropriate for the evaluation of children and, thus, such tests are included in the paragraph B functional parameters. The functional restrictions in paragraph B must be the result of the mental disorder which is manifested by the medical findings in paragraph A.

We have not included separate C criteria for listings 112.03 and 112.06, as are found in the adult listings, because for the most part we do not believe that categories like residual schizophrenia or agoraphobia are commonly found in children. However, in unusual cases where these disorders are found in children and are comparable to the severity and duration found in adults, the adult 12.03C and 12.06C criteria may be used for evaluation of the cases.

The structure of the listings for Mental Retardation (112.05) and Developmental and Emotional Disorders of Newborn and Younger Infants (112.12) is different from that of the other mental disorders. Listing 112.05 (Mental Retardation) contains six sets of criteria, any one of which, if satisfied, will result in a finding that the child's impairment meets the listing. Listing 112.12 (Developmental and Emotional Disorders of Newborn and Younger Infants) contains five criteria, any one of which, if satisfied, will result in a finding that the infant's impairment meets the listing.

It must be remembered that these listings are examples of common mental disorders which are severe enough to find a child disabled. When a child has a medically determinable impairment that is not listed or a combination of impairments no one of which meets a listing, we will make a medical equivalency determination. (See §§404.1526 and 416.926.) This determination can be especially important in older infants and toddlers (age 1 to attainment of age 3), who may be too young for identification of a specific diagnosis, yet demonstrate serious functional limitations. Therefore, the determination of equivalency is necessary to the eval-

uation of any child's case when the child does not have an impairment that meets a listing.

B. Need for Medical Evidence: The existence of a medically determinable impairment of the required duration must be established by medical evidence consisting of symptoms, signs, and laboratory findings (including psychological or developmental test findings). Symptoms are complaints presented by the child. Psychiatric signs are medically demonstrable phenomena which indicate specific abnormalities of behavior, affect, thought, memory, orientation, development, and contact with reality, as described by an appropriate medical source. Symptoms and signs generally cluster together to constitute recognizable mental disorders described in paragraph A of the listings. These findings may be intermittent or continuous depending on the nature of the disorder.

C. Assessment of Severity: In childhood cases, as with adults, severity is measured according to the functional limitations imposed by the medically determinable mental impairment. However, the range of functions used to assess impairment severity for children varies at different stages of maturation. The functional areas that we consider are: Motor function; cognitive/communicative function; social function; personal/behavioral function; and concentration, persistence, and pace. In most functional areas, there are two alternative methods of documenting the required level of severity: (1) Use of standardized tests alone, where appropriate test instruments are available, and (2) use of other medical findings. (See 112.00D for explanation of these documentation requirements.) The use of standardized tests is the preferred method of documentation if such tests are available.

Newborn and younger infants (birth to attainment of age 1) have not developed sufficient personality differentiation to permit formulation of appropriate diagnoses. We have, therefore, assigned listing 112.12 for Developmental and Emotional Disorders of Newborn and Younger Infants for the evaluation of mental disorders of such children. Severity of these disorders is based on measures of development in motor, cognitive/communicative, and social functions. When older infants and toddlers (age 1 to attainment of age 3) do not clearly satisfy the paragraph A criteria of any listing because of insufficient developmental differentiation, they must be evaluated under the rules for equivalency. The principles for assessing the severity of impairment in such children, described in the following paragraphs, must be employed.

In defining the severity of functional limitations, two different sets of paragraph B criteria corresponding to two separate age groupings have been established, in addition to listing 112.12, which is for children who

have not attained age 1. These age groups are: older infants and toddlers (age 1 to attainment of age 3) and children (age 3 to attainment of age 18). However, the discussion below in 112.00C1, 2, 3, and 4, on the age-appropriate areas of function, is broken down into four age groupings: older infants and toddlers (age 1 to attainment of age 3), preschool children (age 3 to attainment of age 6), primary school children (age 6 to attainment of age 12), and adolescents (age 12 to attainment of age 18). This was done to provide specific guidance on the age group variances in disease manifestations and methods of evaluation.

Where "marked" is used as a standard for measuring the degree of limitation it means more than moderate but less than extreme. A marked limitation may arise when several activities or functions are impaired, or even when only one is impaired, as long as the degree of limitation is such as to interfere seriously with the ability to function (based upon age-appropriate expectations) independently, appropriately, effectively, and on a sustained basis. When standardized tests are used as the measure of functional parameters, a valid score that is two standard deviations below the norm for the test will be considered a marked restriction.

1. *Older infants and toddlers (age 1 to attainment of age 3).* In this age group, impairment severity is assessed in three areas: (a) Motor development, (b) cognitive/communicative function, and (c) social function.

a. *Motor development.* Much of what we can discern about mental function in these children frequently comes from observation of the degree of development of fine and gross motor function. Developmental delay, as measured by a good developmental milestone history confirmed by medical examination, is critical. This information will ordinarily be available in the existing medical evidence from the claimant's treating sources and other medical sources, supplemented by information from nonmedical sources, such as parents, who have observed the child and can provide pertinent historical information. It may also be available from standardized testing. If the delay is such that the older infant or toddler has not achieved motor development generally acquired by children no more than one-half the child's chronological age, the criteria are satisfied.

b. *Cognitive/communicative function.* Cognitive/communicative function is measured using one of several standardized infant scales. Appropriate tests for the measure of such function are discussed in 112.00D. Care should be taken to avoid reliance on screening devices, which are not generally considered to be sufficiently reliable instruments, although such devices may provide some relevant data; however, there will be cases in which the results of such tests show such se-

vere abnormalities that further testing will be unnecessary.

For older infants and toddlers, alternative criteria covering disruption in communication as measured by their capacity to use simple verbal and nonverbal structures to communicate basic needs are provided.

c. *Social function.* Social function in older infants and toddlers is measured in terms of the development of relatedness to people (e.g., bonding and stranger anxiety) and attachment to animate or inanimate objects. Criteria are provided that use standard social maturity scales or alternative criteria that describe marked impairment in socialization.

2. *Preschool children (age 3 to attainment of age 6).* For the age groups including preschool children through adolescence, the functional areas used to measure severity are: (a) Cognitive/communicative function, (b) social function, (c) personal/behavioral function, and (d) deficiencies of concentration, persistence, or pace resulting in frequent failure to complete tasks in a timely manner. After 36 months, motor function is no longer felt to be a primary determinant of mental function, although, of course, any motor abnormalities should be documented and evaluated.

a. *Cognitive/communicative function.* In the preschool years and beyond, cognitive function can be measured by standardized tests of intelligence, although the appropriate instrument may vary with age. A primary criterion for limited cognitive function is a valid verbal, performance, or full scale IQ of 70 or less. The listings also provide alternative criteria, consisting of tests of language development or bizarre speech patterns.

b. *Social function.* Social function is measured by an assessment of a child's relationships with parents, other adults, and peers. These relationships are often observed not only at home but also in preschool programs, where the child's interactions with other children and teachers come under daily scrutiny.

c. *Personal/behavioral function.* This function may be measured by a standardized test of adaptive behavior or by careful description of maladaptive or avoidant behaviors. These behaviors are often observed not only at home but also in preschool programs.

d. *Concentration, persistence, and pace.* This function may be measured through observations of the child in the course of standardized testing and in the course of play.

3. *Primary school children (age 6 to attainment of age 12).* The measures of function here are similar to those for preschool-age children except that the test instruments may change and the capacity to function in the school setting is supplemental information. Standardized measures of academic achievement, e.g., Wide Range Achievement

Test-Revised, Peabody Individual Achievement Test, etc., may be helpful in assessing cognitive impairment. Problems in social functioning, especially in the area of peer relationships, are often observed firsthand by teachers and school nurses. As described in 112.00D, *Documentation*, school records are an excellent source of information concerning function and standardized testing and should always be sought for school-age children.

As it applies to primary school children, the intent of the functional criterion described in paragraph B2d, i.e., deficiencies of concentration, persistence, or pace resulting in failure to complete tasks in a timely manner, is to identify the child who cannot adequately function in primary school because of a mental impairment. Although grades and the need for special education placement are relevant factors which must be considered in reaching a decision under paragraph B2d, they are not conclusive. There is too much variability from school district to school district in the expected level of grading and in the criteria for special education placement to justify reliance solely on these factors.

4. *Adolescents (age 12 to attainment of age 18)*. Functional criteria parallel to those for primary school children (cognitive/communicative; social; personal/behavioral; and concentration, persistence, and pace) are the measure of severity for this age group. Testing instruments appropriate to adolescents should be used where indicated. Comparable findings of disruption of social function must consider the capacity to form appropriate, stable, and lasting relationships. If information is available about cooperative working relationships in school or at part-time or full-time work, or about the ability to work as a member of a group, it should be considered when assessing the child's social and personal/behavioral functioning. Markedly impoverished social contact, isolation, withdrawal, and inappropriate or bizarre behavior under the stress of socializing with others also constitute comparable findings.

In adolescents, the intent of the functional criterion described in paragraph B2d is the same as in primary school children. However, other evidence of this functional impairment may also be available, such as from evidence of the child's performance in work or work-like settings.

D. *Documentation*: The presence of a mental disorder in a child must be documented on the basis of reports from acceptable sources of medical evidence. See §§404.1513 and 416.913. Descriptions of functional limitations may be available from these sources, either in the form of standardized test results or in other medical findings supplied by the sources, or both. (Medical findings consist of symptoms, signs, and laboratory findings.) Whenever possible, a medical source's findings should reflect the medical source's

consideration of information from parents or other concerned individuals who are aware of the child's activities of daily living, social functioning, and ability to adapt to different settings and expectations, as well as the medical source's findings and observations on examination, consistent with standard clinical practice. As necessary, information from nonmedical sources, such as parents, should also be used to supplement the record of the child's functioning to establish the consistency of the medical evidence and longitudinality of impairment severity.

For some newborn and younger infants, it may be very difficult to document the presence or severity of a mental disorder. Therefore, with the exception of some genetic diseases and catastrophic congenital anomalies, it may be necessary to defer making a disability decision until the child attains 3 months of age in order to obtain adequate observation of behavior or affect. See, also, 110.00 of this part. This period could be extended in cases of premature infants depending on the degree of prematurity and the adequacy of documentation of their developmental and emotional status.

For infants and toddlers, programs of early intervention involving occupational, physical, and speech therapists, nurses, social workers, and special educators, are a rich source of data. They can provide the developmental milestone evaluations and records on the fine and gross motor functioning of these children. This information is valuable and can complement the medical examination by a physician or psychologist. A report of an interdisciplinary team that contains the evaluation and signature of an acceptable medical source is considered acceptable medical evidence rather than supplemental data.

In children with mental disorders, particularly those requiring special placement, school records are a rich source of data, and the required reevaluations at specified time periods can provide the longitudinal data needed to trace impairment progression over time.

In some cases where the treating sources lack expertise in dealing with mental disorders of children, it may be necessary to obtain evidence from a psychiatrist, psychologist, or pediatrician with experience and skill in the diagnosis and treatment of mental disorders as they appear in children. In these cases, however, every reasonable effort must be made to obtain the records of the treating sources, since these records will help establish a longitudinal picture that cannot be established through a single purchased examination.

A reference to standardized psychological testing indicates the use of a psychological test that has appropriate characteristics of validity, reliability, and norms, administered individually by psychologist, psychia-

trist, pediatrician, or other physician specialist qualified by training and experience to perform such an evaluation. Psychological tests are best considered as sets of tasks or questions designed to elicit particular behaviors when presented in a standardized manner.

The salient characteristics of a good test are: (1) Validity, i.e., the test measures what it is supposed to measure, as determined by appropriate methods; (2) reliability, i.e., the consistency of results obtained over time with the same test and the same individual; and (3) appropriate normative data, i.e., individual test scores must be comparable to test data from other individuals or groups of a similar nature, representative of that population. In considering the validity of a test result, any discrepancies between formal test results and the child's customary behavior and daily activities should be duly noted and resolved.

Tests meeting the above requirements are acceptable for the determination of the conditions contained in these listings. The psychologist, psychiatrist, pediatrician, or other physician specialist administering the test must have a sound technical and professional understanding of the test and be able to evaluate the research documentation related to the intended application of the test.

Identical IQ scores obtained from different tests do not always reflect a similar degree of intellectual functioning. The IQ scores in listing 112.05 reflect values from tests of general intelligence that have a mean of 100 and a standard deviation of 15, e.g., the Wechsler series and the Revised Stanford-Binet scales. Thus, IQ's below 60 reflect a level of intellectual functioning below 99.5 percent of the general population, and IQ's of 70 and below are characteristic of approximately the lowest 2 percent of the general population. IQ's obtained from standardized tests that deviate significantly from a mean of 100 and standard deviation of 15 require conversion to the corresponding percentile rank in the general population so that the actual degree of impairment reflected by the IQ scores can be determined. In cases where more than one IQ is customarily derived from the test administered, e.g., where verbal, performance, and full scale IQ's are provided, as on the Wechsler series, the lowest of these is used in conjunction with listing 112.05.

IQ test results must also be sufficiently current for accurate assessment under 112.05. Generally, the results of IQ tests tend to stabilize by the age of 16. Therefore, IQ test results obtained at age 16 or older should be viewed as a valid indication of the child's current status, provided they are compatible with the child's current behavior. IQ test results obtained between ages 7 and 16 should be considered current for 4 years when the tested IQ is less than 40, and for 2 years when the IQ is 40 or above. IQ test results obtained

before age 7 are current for 2 years if the tested IQ is less than 40 and 1 year if at 40 or above.

Standardized intelligence test results are essential to the adjudication of all cases of mental retardation that are not covered under the provisions of listings 112.05A, 112.05B, and 112.05F. Listings 112.05A, 112.05B, and 112.05F may be the bases for adjudicating cases where the results of standardized intelligence tests are unavailable, e.g., where the child's young age or condition precludes formal standardized testing.

In conjunction with clinical examinations, sources may report the results of screening tests, i.e., tests used for gross determination of level of functioning. These tests do not have high validity and reliability and generally are not considered appropriate primary evidence for disability determinations. These screening instruments may be useful in uncovering potentially serious impairments, but generally must be supplemented by the use of formal, standardized psychological testing for the purposes of a disability determination, unless the determination is to be made on the basis of findings other than psychological test data; however, there will be cases in which the results of screening tests show such obvious abnormalities that further testing will clearly be unnecessary.

Where reference is made to developmental milestones, this is defined as the attainment of particular mental or motor skills at an age-appropriate level, i.e., the skills achieved by an infant or toddler sequentially and within a given time period in the motor and manipulative areas, in general understanding and social behavior, in self-feeding, dressing, and toilet training, and in language. This is sometimes expressed as a developmental quotient (DQ), the relation between developmental age and chronological age as determined by specific standardized measurements and observations. Such tests include, but are not limited to, the Cattell Infant Intelligence Scale, the Bayley Scales of Infant Development, and the Revised Stanford-Binet. Formal tests of the attainment of developmental milestones are generally used in the clinical setting for determination of the developmental status of infants and toddlers.

Formal psychological tests of cognitive functioning are generally in use for preschool children, for primary school children, and for adolescents except for those instances noted below.

Exceptions to formal standardized psychological testing may be considered when a psychologist, psychiatrist, pediatrician, or other physician specialist who is qualified by training and experience to perform such an evaluation is not readily available. In such instances, appropriate medical, historical,

social, and other information must be reviewed in arriving at a determination.

Exceptions may also be considered in the case of ethnic/cultural minorities where the native language or culture is not principally English-speaking. In such instances, psychological tests that are culture-free, such as the Leiter International Performance Scale or the Scale of Multi-Culture Pluralistic Assessment (SOMPA) may be substituted for the standardized tests described above. Any required tests must be administered in the child's principal language. When this is not possible, appropriate medical, historical, social, and other information must be reviewed in arriving at a determination. Furthermore, in evaluating mental impairments in children from a different culture, the best indicator of severity is often the level of adaptive functioning and how the child performs activities of daily living and social functioning.

Neuropsychological testing refers to the administration of standardized tests that are reliable and valid with respect to assessing impairment in brain functioning. It is intended that the psychologist or psychiatrist using these tests will be able to evaluate the following functions: Attention/concentration, problem-solving, language, memory, motor, visual-motor and visual-perceptual, laterality, and general intelligence (if not previously obtained).

E. Effect of Hospitalization or Residential Placement: As with adults, children with mental disorders may be placed in a variety of structured settings outside the home as part of their treatment. Such settings include, but are not limited to, psychiatric hospitals, developmental disabilities facilities, residential treatment centers and schools, community-based group homes, and workshop facilities. The reduced mental demands of such structured settings may attenuate overt symptomatology and superficially make the child's level of adaptive functioning appear better than it is. Therefore, the capacity of the child to function outside highly structured settings must be considered in evaluating impairment severity. This is done by determining the degree to which the child can function (based upon age-appropriate expectations) independently, appropriately, effectively, and on a sustained basis outside the highly structured setting.

On the other hand, there may be a variety of causes for placement of a child in a structured setting which may or may not be directly related to impairment severity and functional ability. Placement in a structured setting in and of itself does not equate with a finding of disability. The severity of the impairment must be compared with the requirements of the appropriate listing.

F. Effects of Medication: Attention must be given to the effect of medication on the child's signs, symptoms, and ability to func-

tion. While psychoactive medications may control certain primary manifestations of a mental disorder, e.g., hallucinations, impaired attention, restlessness, or hyperactivity, such treatment may or may not affect the functional limitations imposed by the mental disorder. In cases where overt symptomatology is attenuated by the psychoactive medications, particular attention must be focused on the functional limitations which may persist. These functional limitations must be considered in assessing impairment severity.

Psychotropic medicines used in the treatment of some mental illnesses may cause drowsiness, blunted affect, or other side effects involving other body systems. Such side effects must be considered in evaluating overall impairment severity.

11.01 Category of Impairments, Mental

11.02 Organic Mental Disorders: Abnormalities in perception, cognition, affect, or behavior associated with dysfunction of the brain. The history and physical examination or laboratory tests, including psychological or neuropsychological tests, demonstrate or support the presence of an organic factor judged to be etiologically related to the abnormal mental state and associated deficit or loss of specific cognitive abilities, or affective changes, or loss of previously acquired functional abilities.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence of at least one of the following:

1. Developmental arrest, delay or regression; or
2. Disorientation to time and place; or
3. Memory impairment, either short-term (inability to learn new information), intermediate, or long-term (inability to remember information that was known sometime in the past); or
4. Perceptual or thinking disturbance (e.g., hallucinations, delusions, illusions, or paranoid thinking); or
5. Disturbance in personality (e.g., apathy, hostility); or
6. Disturbance in mood (e.g., mania, depression); or
7. Emotional lability (e.g., sudden crying); or
8. Impairment of impulse control (e.g., disinhibited social behavior, explosive temper outbursts); or
9. Impairment of cognitive function, as measured by clinically timely standardized psychological testing; or
10. Disturbance of concentration, attention, or judgment;

AND

B. Select the appropriate age group to evaluate the severity of the impairment:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the following:

a. Gross or fine motor development at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings (see 112.00C); or

b. Cognitive/communicative function at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings of equivalent cognitive/communicative abnormality, such as the inability to use simple verbal or nonverbal behavior to communicate basic needs or concepts; or

c. Social function at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings of an equivalent abnormality of social functioning, exemplified by serious inability to achieve age-appropriate autonomy as manifested by excessive clinging or extreme separation anxiety; or

d. Attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in two or more areas covered by a., b., or c., as measured by an appropriate standardized test or other appropriate medical findings.

2. For children (age 3 to attainment of age 18), resulting in at least two of the following:

a. Marked impairment in age-appropriate cognitive/communicative function, documented by medical findings (including consideration of historical and other information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, the results of appropriate standardized psychological tests, or for children under age 6, by appropriate tests of language and communication; or

b. Marked impairment in age-appropriate social functioning, documented by history and medical findings (including consideration of information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, the results of appropriate standardized tests; or

c. Marked impairment in personal/behavioral function, as evidenced by:

(1) Marked restriction of age-appropriate activities of daily living, documented by history and medical findings (including consideration of information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, appropriate standardized tests; or

(2) Persistent serious maladaptive behaviors destructive to self, others, animals, or property, requiring protective intervention; or

d. Deficiencies of concentration, persistence, or pace resulting in frequent failure to complete tasks in a timely manner.

112.03 *Schizophrenic, Delusional (Paranoid), Schizoaffective, and Other Psychotic Disorders*: Onset of psychotic features, characterized by a marked disturbance of thinking, feeling, and behavior, with deterioration from a previous level of functioning or failure to achieve the expected level of social functioning.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence, for at least 6 months, either continuous or intermittent, of one or more of the following:

1. Delusions or hallucinations; or

2. Catatonic, bizarre, or other grossly disorganized behavior; or

3. Incoherence, loosening of associations, illogical thinking, or poverty of content of speech; or

4. Flat, blunt, or inappropriate affect; or

5. Emotional withdrawal, apathy, or isolation; and

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.04 *Mood Disorders*: Characterized by a disturbance of mood (referring to a prolonged emotion that colors the whole psychic life, generally involving either depression or elation), accompanied by a full or partial manic or depressive syndrome.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence, either continuous or intermittent, of one of the following:

1. Major depressive syndrome, characterized by at least five of the following, which must include either depressed or irritable mood or markedly diminished interest or pleasure:

a. Depressed or irritable mood; or

b. Markedly diminished interest or pleasure in almost all activities; or

c. Appetite or weight increase or decrease, or failure to make expected weight gains; or

d. Sleep disturbance; or

e. Psychomotor agitation or retardation; or

f. Fatigue or loss of energy; or

g. Feelings of worthlessness or guilt; or

h. Difficulty thinking or concentrating; or

1. Suicidal thoughts or acts; or
 J. Hallucinations, delusions, or paranoid thinking;

OR

2. Manic syndrome, characterized by elevated, expansive, or irritable mood, and at least three of the following:

- a. Increased activity or psychomotor agitation; or
- b. Increased talkativeness or pressure of speech; or
- c. Flight of ideas or subjectively experienced racing thoughts; or
- d. Inflated self-esteem or grandiosity; or
- e. Decreased need for sleep; or
- f. Easy distractibility; or
- g. Involvement in activities that have a high potential of painful consequences which are not recognized; or
- h. Hallucinations, delusions, or paranoid thinking;

OR

3. Bipolar or cyclothymic syndrome with a history of episodic periods manifested by the full symptomatic picture of both manic and depressive syndromes (and currently or most recently characterized by the full or partial symptomatic picture of either or both syndromes);

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.05 *Mental Retardation*: Characterized by significantly subaverage general intellectual functioning with deficits in adaptive functioning.

The required level of severity for this disorder is met when the requirements in A, B, C, D, E, or F are satisfied.

A. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02;

OR

B. Mental incapacity evidenced by dependence upon others for personal needs (grossly in excess of age-appropriate dependence) and inability to follow directions such that the use of standardized measures of intellectual functioning is precluded;

OR

C. A valid verbal, performance, or full scale IQ of 59 or less;

OR

D. A valid verbal, performance, or full scale IQ of 60 through 70 and a physical or

other mental impairment imposing additional and significant limitation of function;

OR

E. A valid verbal, performance, or full scale IQ of 60 through 70 and:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in either paragraphs B1a or B1c of 112.02; or

2. For children (age 3 to attainment of age 18), resulting in at least one of paragraphs B2b or B2c or B2d of 112.02;

OR

F. Select the appropriate age group:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in paragraph B1b of 112.02, and a physical or other mental impairment imposing additional and significant limitations of function;

OR

2. For children (age 3 to attainment of age 18), resulting in the satisfaction of 112.02B2a, and a physical or other mental impairment imposing additional and significant limitations of function.

112.06 *Anxiety Disorders*: In these disorders, anxiety is either the predominant disturbance or is experienced if the individual attempts to master symptoms, e.g., confronting the dreaded object or situation in a phobic disorder, attempting to go to school in a separation anxiety disorder, resisting the obsessions or compulsions in an obsessive compulsive disorder, or confronting strangers or peers in avoidant disorders.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of at least one of the following:

1. Excessive anxiety manifested when the child is separated, or separation is threatened, from a parent or parent surrogate; or

2. Excessive and persistent avoidance of strangers; or

3. Persistent unrealistic or excessive anxiety and worry (apprehensive expectation), accompanied by motor tension, autonomic hyperactivity, or vigilance and scanning; or

4. A persistent irrational fear of a specific object, activity, or situation which results in a compelling desire to avoid the dreaded object, activity, or situation; or

5. Recurrent severe panic attacks, manifested by a sudden unpredictable onset of intense apprehension, fear, or terror, often with a sense of impending doom, occurring on the average of at least once a week; or

6. Recurrent obsessions or compulsions which are a source of marked distress; or

7. Recurrent and intrusive recollections of a traumatic experience, including dreams, which are a source of marked distress;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.07 *Somatoform, Eating, and Tic Disorders*: Manifested by physical symptoms for which there are no demonstrable organic findings or known physiologic mechanisms; or eating or tic disorders with physical manifestations.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of one of the following:

1. An unrealistic fear and perception of fatness despite being underweight, and persistent refusal to maintain a body weight which is greater than 85 percent of the average weight for height and age, as shown in the most recent edition of the *Nelson Textbook of Pediatrics*, Richard E. Behrman and Victor C. Vaughan, III, editors, Philadelphia: W. B. Saunders Company; or

2. Persistent and recurrent involuntary, repetitive, rapid, purposeless motor movements affecting multiple muscle groups with multiple vocal tics; or

3. Persistent nonorganic disturbance of one of the following:

- a. Vision; or
- b. Speech; or
- c. Hearing; or
- d. Use of a limb; or
- e. Movement and its control (e.g., coordination disturbance, psychogenic seizures); or
- f. Sensation (diminished or heightened); or
- g. Digestion or elimination; or

4. Preoccupation with a belief that one has a serious disease or injury;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.08 *Personality Disorders*: Manifested by pervasive, inflexible, and maladaptive personality traits, which are typical of the child's long-term functioning and not limited to discrete episodes of illness.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Deeply ingrained, maladaptive patterns of behavior, associated with one of the following:

1. Seclusiveness or autistic thinking; or

2. Pathologically inappropriate suspiciousness or hostility; or

3. Oddities of thought, perception, speech, and behavior; or

4. Persistent disturbances of mood or affect; or

5. Pathological dependence, passivity, or aggressiveness; or

6. Intense and unstable interpersonal relationships and impulsive and exploitative behavior; or

7. Pathological perfectionism and inflexibility;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.09 *Psychoactive Substance Dependence Disorders*: Manifested by a cluster of cognitive, behavioral, and physiologic symptoms that indicate impaired control of psychoactive substance use with continued use of the substance despite adverse consequences.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of at least four of the following:

1. Substance taken in larger amounts or over a longer period than intended and a great deal of time is spent in recovering from its effects; or

2. Two or more unsuccessful efforts to cut down or control use; or

3. Frequent intoxication or withdrawal symptoms interfering with major role obligations; or

4. Continued use despite persistent or recurring social, psychological, or physical problems; or

5. Tolerance, as characterized by the requirement for markedly increased amounts of substance in order to achieve intoxication; or

6. Substance taken to relieve or avoid withdrawal symptoms;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.10 *Autistic Disorder and Other Pervasive Developmental Disorders*: Characterized by qualitative deficits in the development of reciprocal social interaction, in the development of verbal and nonverbal communication skills, and in imaginative activity.

Often, there is a markedly restricted repertoire of activities and interests, which frequently are stereotyped and repetitive.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of the following:

1. For autistic disorder, all of the following:

a. Qualitative deficits in the development of reciprocal social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity; and

c. Markedly restricted repertoire of activities and interests;

OR

2. For pervasive developmental disorders, both of the following:

a. Qualitative deficits in the development of social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraphs B2 of 112.02.

112.11 Attention Deficit Hyperactivity Disorder: Manifested by developmentally inappropriate degrees of inattention, impulsiveness, and hyperactivity.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of all three of the following:

1. Marked inattention; and
2. Marked impulsiveness; and
3. Marked hyperactivity;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.12 Developmental and Emotional Disorders of Newborn and Younger Infants (Birth to attainment of age 1): Developmental or emotional disorders of infancy are evidenced by a deficit or lag in the areas of motor, cognitive/communicative, or social functioning. These disorders may be related either to organic or to functional factors or to a combination of these factors.

The required level of severity for these disorders is met when the requirements of A, B, C, D, or E are satisfied.

A. Cognitive/communicative functioning generally acquired by children no more than one-half the child's chronological age, as documented by appropriate medical findings (e.g., in infants 0-6 months, markedly diminished variation in the production or imitation of sounds and severe feeding abnormality, such as problems with sucking, swallowing, or chewing) including, if necessary, a standardized test;

OR

B. Motor development generally acquired by children no more than one-half the child's chronological age, documented by appropriate medical findings, including if necessary, a standardized test;

OR

C. Apathy, over-excitability, or fearfulness, demonstrated by an absent or grossly excessive response to one of the following:

1. Visual stimulation; or
2. Auditory stimulation; or
3. Tactile stimulation;

OR

D. Failure to sustain social interaction on an ongoing, reciprocal basis as evidenced by:

1. Inability by 6 months to participate in vocal, visual, and motoric exchanges (including facial expressions); or
2. Failure by 9 months to communicate basic emotional responses, such as cuddling or exhibiting protest or anger; or
3. Failure to attend to the caregiver's voice or face or to explore an inanimate object for a period of time appropriate to the infant's age;

OR

E. Attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in two or more areas (i.e., cognitive/communicative, motor, and social), documented by appropriate medical findings, including if necessary, standardized testing.

113.00 NEOPLASTIC DISEASES, MALIGNANT

A. *Introduction.* Determination of disability in the growing and developing child with a malignant neoplastic disease is based upon the combined effects of:

1. The pathophysiology, histology, and natural history of the tumor; and
2. The effects of the currently employed aggressive multimodal therapeutic regimens.

Combinations of surgery, radiation, and chemotherapy or prolonged therapeutic schedules impart significant additional morbidity to the child during the period of greatest risk from the tumor itself. This period of highest risk and greatest therapeutically-induced morbidity defines the limits of disability for most of childhood neoplastic disease.

B. *Documentation.* The diagnosis of neoplasm should be established on the basis of symptoms, signs, and laboratory findings.

The site of the primary, recurrent, and metastatic lesion must be specified in all cases of malignant neoplastic diseases. If an operative procedure has been performed, the evidence should include a copy of the operative note and the report of the gross and microscopic examination of the surgical specimen, along with all pertinent laboratory and X-ray reports. The evidence should also include a recent report directed especially at describing whether there is evidence of local or regional recurrence, soft part or skeletal metastases, and significant post therapeutic residuals.

C. *Malignant solid tumors*, as listed under 113.03, include the histiocytosis syndromes except for solitary eosinophilic granuloma. Thus, 113.03 should not be used for evaluating brain tumors (see 111.05) or thyroid tumors, which must be evaluated on the basis of whether they are controlled by prescribed therapy.

D. *Duration of disability* from malignant neoplastic tumors is included in 113.02 and 113.03. Following the time periods designated in these sections, a documented diagnosis itself is no longer sufficient to establish a severe impairment. The severity of a remaining impairment must be evaluated on the basis of the medical evidence.

113.01 *Category of Impairments, Neoplastic Diseases—Malignant*
 113.02 *Lymphoreticular* *malignant neoplasms.*

A. Hodgkin's disease with progressive disease not controlled by prescribed therapy; or

B. Non-Hodgkin's lymphoma. Consider under a disability:

1. For 2½ years from time of initial diagnosis; or

2. For 2½ years from time of recurrence of active disease.

113.03 *Malignant solid tumors*. Consider under a disability:

A. For 2 years from the time of initial diagnosis; or

B. For 2 years from the time of recurrence of active disease.

113.04 *Neuroblastoma*. With one of the following:

A. Extension across the midline; or

B. Distant metastases; or

C. Recurrence; or

D. Onset at age 1 year or older.

113.05 *Retinoblastoma*. With one of the following:

A. Bilateral involvement; or

B. Metastases; or

C. Extension beyond the orbit; or

D. Recurrence.

114.00 IMMUNE SYSTEM

A. Listed disorders include impairments involving deficiency of one or more components of the immune system (i.e., antibody-producing B cells; a number of different types of cells associated with cell-mediated

immunity including T-lymphocytes, macrophages and monocytes; and components of the complement system).

B. Dysregulation of the immune system may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. These disorders are described in part A, 14.00B.

Some of the features of connective tissue disorders in children may differ from the features in adults. When the clinical features are the same as that seen in adults, the principles and concepts in part A, 14.00B apply.

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, medically acceptable imaging techniques and, in some instances, tissue biopsy. However, the Social Security Administration will not purchase diagnostic tests or procedures that may involve significant risk, such as biopsies or angiograms. Generally, the existing medical evidence will contain this information.

In addition to the limitations caused by the connective tissue disorder *per se*, the chronic adverse effects of treatment (e.g., corticosteroid-related ischemic necrosis of bone) may result in functional loss.

A longitudinal clinical record of at least 3 months demonstrating active disease despite prescribed treatment during this period with the expectation that the disease will remain active for 12 months is necessary for assessment of severity and duration of impairment.

In children the impairment may affect growth, development, attainment of age-appropriate skills, and performance of age-appropriate activities. The limitations may be the result of loss of function or failure in a single organ or body system, or a lesser degree of functional loss in two or more organs/body systems that, in combination with significant constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss, results in listing-level limitations. We use the term "severe" in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§ 404.1520, 416.920, and 416.924.

C. Allergies, growth impairments and Kawasaki disease.

1. Allergic disorders (e.g., asthma or atopic dermatitis) are discussed and evaluated under the appropriate listing of the affected body system.

2. If growth is affected by the disorder or its treatment by immunosuppressive drugs, 100.00 may apply.

3. Kawasaki disease, also known as mucocutaneous lymph node syndrome, is characterized by multisystem manifesta-

tions, but significant functional impairment is usually due to disease of the coronary arteries, which should be evaluated under 104.00.

D. Human Immunodeficiency virus (HIV) infection.

1. HIV infection is caused by a specific retrovirus and may be characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions, as described in 114.08. Any child with HIV infection, including one with a diagnosis of acquired immunodeficiency syndrome (AIDS), may be found disabled under this listing if his or her impairment meets any of the criteria in 114.08 or is of equivalent severity to an impairment in 114.08.

2. Definitions. In 114.08, the terms "resistant to treatment," "recurrent," and "disseminated" have the same general meaning as used by the medical community. The precise meaning of any of these terms will depend upon the specific disease or condition in question, the body system affected, the usual course of the disorder and its treatment, and the other circumstances of the case.

"Resistant to treatment" means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate, or a course of treatment appropriate, will depend on the facts of the particular case.

"Recurrent" means that a condition that responded adequately to an appropriate course of treatment has returned after a period of remission or regression. The extent of response (or remission) and the time periods involved will depend on the facts of the particular case.

"Disseminated" means that a condition is spread widely over a considerable area or body system(s). The type and extent of the spread will depend on the specific disease.

3. Documentation of HIV infection in children. The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of HIV infection in children by definitive diagnosis. A definitive diagnosis of HIV infection in children is documented by one or more of the following laboratory tests:

1. For a child 24 months of age or older, a serum specimen that contains HIV antibodies. HIV antibodies are usually detected by a screening test. The most commonly used screening test is the ELISA. Although this test is highly sensitive, it may yield false positive results. Therefore, positive results from an ELISA must be confirmed by a more definitive test (e.g., Western blot, immunofluorescence assay). (See paragraph b, below, for information about HIV antibody

testing in children younger than 24 months of age).

ii. A specimen that contains HIV antigen (e.g., serum specimen, lymphocyte culture, or cerebrospinal fluid (CSF) specimen).

iii. An immunoglobulin A (IgA) serological assay specific for HIV.

iv. Other test(s) that are highly specific for detection of HIV in children (e.g., polymerase chain reaction (PCR)), or that are acceptable methods of detection consistent with the prevailing state of medical knowledge.

When laboratory testing for HIV infection has been performed, every reasonable effort must be made to obtain reports of the results of that testing.

b. Other acceptable documentation of HIV infection in children.

As noted in paragraph a, above, HIV infection is not documented in children under 24 months of age by a serum specimen containing HIV antibodies. This is because women with HIV infection often transfer HIV antibodies to their newborns. The mother's antibodies can persist in the infant for up to 24 months, even if the infant is not HIV-infected. Only 20 to 30 percent of such infants are actually infected. Therefore, the presence of serum HIV antibodies alone does not establish the presence of HIV infection in a child under 24 months of age. However, the presence of HIV antibodies accompanied by evidence of significantly depressed T-helper lymphocytes (CD4), an abnormal CD4/CD8 ratio, or abnormal immunoglobulin G (IgG) may be used to document HIV infection in a child under 24 months of age, even though such testing is not a basis for a definitive diagnosis.

For children from birth to the attainment of 24 months of age who have tested positive for HIV antibodies (see D3a above), HIV infection may be documented by one or more of the following:

i. For an infant 12 months of age or less, a CD4 (T4) count of 1500/mm³ or less, or a CD4 count less than or equal to 20 percent of total lymphocytes.

ii. For an infant from 12 to 24 months of age, a CD4 (T4) count of 750/mm³ or less, or a CD4 count less than or equal to 20 percent of total lymphocytes.

iii. An abnormal CD4/CD8 ratio.

iv. An IgG significantly greater than or less than the normal range for age.

HIV infection in children may also be documented without the definitive laboratory evidence described in paragraph a, or the other laboratory evidence discussed above, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If such laboratory evidence is not available, HIV infection may be documented by the medical history, clinical and laboratory findings, and

diagnosis(es) indicated in the medical evidence. For example, a diagnosis of HIV infection in children will be accepted without definitive laboratory evidence if the child has an opportunistic disease (e.g., *Pneumocystis carinii* pneumonia (PCP)) predictive of a defect in cell-mediated immunity, and there is no other known cause of diminished resistance to that disease (e.g., long-term steroid treatment, lymphoma). In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

4. Documentation of the manifestations of HIV infection in children. The medical evidence must also include documentation of the manifestations of HIV infection in children. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of the manifestations of HIV infection in children by definitive diagnosis.

The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection in children is by culture, serological test, or microscopic examination of biopsied tissue or other material (e.g., bronchial washings). Therefore, every reasonable effort must be made to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histological or other test has been performed, the evidence should include a copy of the appropriate report. If the report is not obtainable, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including radiographic studies) or microscopic examination of the appropriate tissues or body fluids.

Although a reduced CD4 lymphocyte count in a child may show that there is an increased susceptibility to opportunistic infections and diseases, that alone does not document the presence, severity, or functional effects of a manifestation of HIV infection in a child.

b. Other acceptable documentation of the manifestations of HIV infection in children.

Manifestations of HIV infection in children may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, manifestations of HIV infection may be documented by medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

Documentation of cytomegalovirus (CMV) disease (114.08D) presents special problems because diagnosis requires identification of viral inclusion bodies or a positive culture from the affected organ, and the absence of any other infectious agent. A positive serology test identifies infection with the virus, but does not confirm a disease process. With the exception of chorioretinitis (which may be diagnosed by an ophthalmologist), documentation of CMV disease requires confirmation by biopsy or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

5. HIV infection in children. The clinical manifestation and course of disease in children who become infected with HIV perinatally or in the first 6 years of life may differ from that in older children and adults. In addition, survival times are shorter for children infected in the first year of life compared to those who become infected as older children or as adults. Infants may present with failure to thrive or *pneumocystis carinii* pneumonia (PCP); young children may present with recurrent infections, neurological problems, or developmental abnormalities. Older children may also exhibit neurological abnormalities, such as HIV encephalopathy, or failure to thrive.

The methods of identifying and evaluating neurological abnormalities may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In older children, impaired brain growth can be documented by brain atrophy on a CAT scan. Neurological abnormalities can also be observed in a younger child in the loss of previously acquired, or marked delays in achieving, developmental milestones. In an older child, this type of neurological abnormality would generally be demonstrated by the loss of previously acquired intellectual abilities. Although loss of previously acquired intellectual abilities can be documented by a decrease in intelligence quotient (IQ) scores or demonstrated if a child forgets information he or she previously learned, it can also be shown if the child is unable to learn new information. This could include the sudden acquisition of a new learning disability.

Children with HIV infection may contract any of a broad range of bacterial infections. Certain major infections caused by pyogenic bacteria, e.g., some pneumonias, can be severely limiting, especially in pre-adolescent children. These major bacterial infections should be evaluated under 114.08A5, which requires two or more such infections within a 2-year period. Although 114.08A5 applies only to children less than 13 years of age, an older child may be found to have an impairment of equivalent severity if the circumstances of the case warrant (e.g., delayed puberty).

Otherwise, bacterial infections are evaluated under 114.08A6. The criteria of the listing are met if one or more bacterial infection(s) occurs and requires hospitalization or intravenous antibiotic treatment 3 or more times in 1 year. Pelvic inflammatory disease in older female children should be evaluated under multiple or recurrent bacterial infections (114.08A6).

6. Evaluation of HIV infection in children. The criteria in 114.08 do not describe the full spectrum of diseases or conditions manifested by children with HIV infection. As in any case, consideration must be given to whether a child's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplastic disorder listed in 113.00ff). Although 114.08 includes cross-references to other listings for the more common manifestations of HIV infection, additional listings may also apply.

In addition, the impact of all impairments, whether or not related to the HIV infection, must be considered. Children with HIV infection may manifest signs and symptoms of a mental impairment (e.g., anxiety, depression), or of another physical impairment. Medical evidence should include documentation of all physical and mental impairments and the impairment(s) should be evaluated not only under the relevant listing(s) in 114.08, but under any other appropriate listing(s).

It is also important to remember that children with HIV infection, like all others, are evaluated under the full sequential evaluation process described in §416.924. If a child with HIV infection is working and engaging in substantial gainful activity (SGA), or does not have a severe impairment, the case will be decided at the first or second step of the sequential evaluation process, and does not require evaluation under these listings. For a child with HIV infection who is not engaging in SGA and has a severe impairment, but whose impairment(s) does not meet the criteria of a listing, consideration will be given to whether the child's impairment or combination of impairments is either medically or functionally equivalent in severity to any listed impairment. If the child's impairment or impairments do not meet or equal a listing in severity, evaluation must proceed through the final step(s) of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard) before any conclusion can be reached on the issue of disability.

7. Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g. antiretroviral agents) and in terms of any side effects of treatment that may further impair the child.

Response to treatment and adverse or beneficial consequences of treatment may vary widely. For example, a child with HIV infection who develops otitis media may respond to the same antibiotic regimen used in treating children without HIV infection, but another child with HIV infection may not respond to the same regimen. Therefore, each case must be considered on an individual basis, along with the effects of treatment on the child's ability to function.

A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long-term. As such, the decision regarding the impact of treatment should be based on a sufficient period of treatment to permit proper consideration.

8. Functional criteria. Paragraph O of 114.08 establishes standards for evaluating manifestations of HIV infection that do not meet the requirements listed in 114.08A-N. Paragraph O is applicable for manifestations that are not listed in 114.08A-N, as well as those listed in 114.08A-N that do not meet the criteria of any of the rules in 114.08A-N.

For children with HIV infection evaluated under 114.08O, listing-level severity will be assessed in terms of the functional limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the child's ability to function must be considered. Important factors to be considered in evaluating the functioning of children with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

To meet the criteria in 114.08O, a child with HIV infection must demonstrate a level of restriction in either one or two (depending on the child's age) of the general areas of functioning applicable to the child's age group. (See 112.00C for additional discussion of these areas of functioning).

114.01 Category of Impairments, Immune System

114.02 Systemic lupus erythematosus. Documented as described in 14.00B1 and 114.00B, with:

A. One of the following:

1. Growth impairment, as described under the criteria in 100.00ff; or
2. Musculoskeletal involvement, as described under the criteria in 101.00ff; or
3. Muscle involvement, as described under the criteria in 14.05; or
4. Ocular involvement, as described under the criteria in 102.00ff; or

5. Respiratory involvement, as described under the criteria in 103.00ff; or

6. Cardiovascular involvement, as described under the criteria in 104.00ff or 14.04D; or

7. Digestive involvement, as described under the criteria in 105.00ff; or

8. Renal involvement, as described under the criteria in 106.00ff; or

9. Hematologic involvement, as described under the criteria in 107.00ff; or

10. Skin involvement, as described under the criteria in 8.00ff; or

11. Endocrine involvement, as described under the criteria in 109.00ff; or

12. Neurological involvement, as described under the criteria in 111.00ff; or

13. Mental involvement, as described under the criteria in 112.00ff.

or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

114.03 *Systemic vasculitis*. As described under the criteria in 14.03 or, if growth impairment, as described under the criteria in 100.00ff.

114.04 *Systemic sclerosis and scleroderma*. Documented as described in 14.00B3 and 114.00B, and:

A. As described under the criteria in 14.04 or, if growth impairment, as described under the criteria in 100.00ff.

or

B. Linear scleroderma, with one of the following:

1. Fixed valgus or varus deformities of both hands or both feet; or

2. Marked destruction or marked atrophy of an extremity; or

3. Facial disfigurement from hypoplasia of the mandible, maxilla, or zygoma resulting in an impairment as described under the criteria in 112.00ff; or

4. Seizure disorder, as described under the criteria in 111.00ff.

114.05 *Polymyositis or dermatomyositis*. Documented as described in 14.00B4 and 114.00B, and:

A. As described under the criteria in 14.05.

or

B. With one of the following:

1. Multiple joint contractures; or

2. Diffuse cutaneous calcification with formation of an exoskeleton; or

3. Systemic vasculitis as described under the criteria in 14.03.

114.06 *Undifferentiated connective tissue disorder*. As described under the criteria in 114.02 or 114.04.

114.07 *Congenital immune deficiency disease*.

A. Hypogammaglobulinemia or dysgammaglobulinemia, with:

1. Documented, recurrent severe infections occurring 3 or more times within a 5-month period; or

2. An associated disorder such as growth retardation, chronic lung disease, collagen disorder or tumor. Evaluate according to the appropriate body system listing.

or

B. Thymic dysplastic syndromes (such as Swiss, diGeorge).

114.08 *Human immunodeficiency virus (HIV) infection*. With documentation as described in 114.00D3 and one of the following:

A. Bacterial infections:

1. Mycobacterial infection (e.g., caused by *M. avium*-intracellulare, *M. kansasii*, or *M. tuberculosis*) at a site other than the lungs, skin, or cervical or hilar lymph nodes; or pulmonary tuberculosis resistant to treatment; or

2. Nocardiosis; or

3. *Salmonella* bacteremia, recurrent nontyphoid.

4. Syphilis or neurosyphilis—evaluate sequelae under the criteria for the affected body system (e.g., 102.00 Special Senses and Speech, 104.00 Cardiovascular System, 111.00 Neurological); or

5. In a child less than 13 years of age, multiple or recurrent pyogenic bacterial infection(s) of the following types: sepsis, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses) occurring 2 or more times in 2 years; or

6. Other multiple or recurrent bacterial infection(s), including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment 3 or more times in 1 year.

or

B. Fungal infections:

1. Aspergillosis; or

2. Candidiasis, at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or candidiasis involving the esophagus, trachea, bronchi, or lungs; or

3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or

4. Cryptococcosis, at a site other than the lungs (e.g., cryptococcal meningitis); or

5. Histoplasmosis, at a site other than the lungs or lymph nodes; or

6. Mucormycosis.

or

C. Protozoan or helminthic infections:

1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or

2. *Pneumocystis carinii* pneumonia or extrapulmonary pneumocystis carinii infection; or

3. Strongyloidiasis, extra-intestinal; or

4. Toxoplasmosis of an organ other than the liver, spleen, or lymph nodes.

or

D. Viral infections:

1. Cytomegalovirus disease (documented as described in 114.00D4b) at a site other than the liver, spleen, or lymph nodes; or

2. Herpes simplex virus causing:

a. Mucocutaneous infection (e.g., oral, genital, perianal) lasting for 1 month or longer; or

b. Infection at a site other than the skin or mucous membranes (e.g., bronchitis, pneumonia, esophagitis, or encephalitis); or

c. Disseminated infection; or

3. Herpes zoster, either disseminated or with multidermatomal eruptions that are resistant to treatment; or

4. Progressive multifocal leukoencephalopathy; or

5. Hepatitis, as described under the criteria of 105.05.

or

E. Malignant neoplasms:

1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or

2. Kaposi's sarcoma with:

a. Extensive oral lesions; or

b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or

c. Involvement of the skin or mucous membranes as described under the criteria of 114.06F; or

3. Lymphoma (e.g., primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other Non-Hodgkin's lymphoma, Hodgkin's disease); or

4. Squamous cell carcinoma of the anus.

or

F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3 above) with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease), or evaluate under the criteria in 8.00ff.

or

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02; or

2. Granulocytopenia, as described under the criteria in 7.15; or

3. Thrombocytopenia, as described under the criteria of 107.06 or 7.06.

or

H. Neurological manifestations of HIV infection (e.g., HIV encephalopathy, peripheral neuropathy), as described under the criteria in 111.00ff, or resulting in one or more of the following:

1. Loss of previously acquired, or marked delay in achieving, developmental milestones or intellectual ability (including the sudden acquisition of a new learning disability); or

2. Impaired brain growth (acquired microcephaly or brain atrophy—see 114.00D5); or

3. Progressive motor dysfunction affecting gait and station or fine and gross motor skills.

or

I. Growth disturbance, with:

1. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) that persists for 2 months or longer; or

2. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) that persists for 2 months or longer; or

3. Involuntary weight loss greater than 10 percent of baseline that persists for 2 months or longer; or

4. Growth impairment as described under the criteria in 100.00ff.

or

J. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.

or

K. Cardiomyopathy, as described under the criteria in 104.00ff or 11.04.

or

L. Lymphoid interstitial pneumonia/pulmonary lymphoid hyperplasia (LIP/PLH complex), with respiratory symptoms that significantly interfere with age-appropriate activities, and that cannot be controlled by prescribed treatment.

or

M. Nephropathy, as described under the criteria in 106.00.

or

N. One or more of the following infections (other than described in A-M, above), resistant to treatment or requiring hospitalization or intravenous treatment 3 or more times in 1 year (or evaluate sequelae under the criteria for the affected body system):

1. Sepsis;

2. Meningitis; or

3. Pneumonia; or

4. Septic arthritis; or

5. Endocarditis; or

6. Radiographically documented sinusitis.

or

O. Any other manifestation(s) of HIV infection (including any listed in 114.08A-N, but without the requisite findings, e.g., oral candidiasis not meeting the criteria in 114.08F, diarrhea not meeting the criteria in 114.06J, or any other manifestation(s), e.g., oral hairy leukoplakia, hepatomegaly), resulting in one of the following:

1. For children from birth to attainment of age 1, at least one of the criteria in paragraphs A-E of 112.12; or

2. For children age 1 to attainment of age 3, at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or

3. For children age 3 to attainment of age 18, at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

[50 FR 35066, Aug. 28, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting appendix 1 to subpart P of part 404, see the List of CFR Sections Affected in the Finding Aids section of this volume.

Senator BYRD. I apologize for the length of time I am consuming, Mr. Chairman. I will not take much longer. Let me ask these questions.

What about people who are drug addicts? Should people who have drug related conditions be subjected to periodic blood tests? If they test positive for illegal substances, should they be dropped from the SSI?

Should the SSI benefit be converted from cash to vouchers for treatment? Does providing cash to addicts address their major problem or does it enable them to continue and to even intensify their drug habit?

There are members of the House and Senate who feel that families in their districts are coaching their children, just what the West Virginia school teacher said, coaching their children to act as if they have a disability, particularly attention and behavioral disorders so they can qualify for SSI cash and medical care.

What could be done to assure that the cash that goes to families actually is used to help the disabled child? The concern of Congress is to help disabled children to get treatment for their condition at public expense.

Should the entitlement for cash be converted into vouchers for treatment, and would that remove the incentive to cheat in order to receive the cash benefit?

No one in his right mind would want to deprive children of needed treatment. But cash subsidies for other family spending is not what Congress intended.

In my judgment, having witnessed this television report and having read the Washington Post story, having read the teacher's letter, it would seem to me that this is a prime example of a well-intentioned entitlement program run amok, and a microcosm of what is wrong with our Federal deficit, not to mention the damage that is being done to our children in teaching them that their future lies not in hard work but in ripping off the Federal Government for benefits.

Now, you have already indicated some actions that are being taken. Mr. Mangano—is that the way it is pronounced?

Mr. MANGANO. That is correct.

Senator BYRD. You have already indicated some actions that are being taken. I do not want to further impose on the time of the subcommittee, but you indicated you were going to complete a report in the month of June.

Let this subcommittee have a copy of that report, please, and given the above circumstances as you prepare the report—and if it is too late to include this in the report think of these questions in preparing another report.

Does it make sense to in effect reward the parent by paying parents each month for a problem that they are creating? Would it be more appropriate to provide vouchers for medical treatment, as I indicated earlier, rather than cash payments?

And I would appreciate the subcommittee having a full report on the following—a review of the Social Security regulations and the recommendations for changes in those regulations to tighten up this program; recommendations for any changes in the law that may be required to make sure that those who are not truly dis-

abled do not receive the benefit; investigations into claims of children being coached, and you indicated earlier that you were looking into those claims, but give special attention to this—investigation of the claims of children being coached by their parents and recommendations for changes in regulations or law.

Four, the appropriateness of providing cash payments to the parents of children when those children are residing in a home where the parents or guardians are abusive, alcoholic, or drug addicts, and recommendations for changes in the regulations and/or the law.

I certainly do not want to take benefits away from children who are truly disabled. I want to help those children. But we have to think about how the programs are being ripped off, and the impact that that has on the taxpayer, how it undermines the program, the confidence in the program, the support for the program, and what it does to the attitude of the children who are able to rip it off.

Do you have any further comments at this time? If you do, I would like to hear them. Otherwise please elaborate on your answers earlier and supply the reports, and answer the questions I have asked in the reports and other questions that occur.

Do you have anything else now?

Mr. MANGANO. Nothing really. The questions you raised are legitimate questions that ought to be debated. When the court passed down on the *Zebley* decision, *Sullivan v. Zebley*, it caused a lot of things to change in that program. We have all seen the effects of that.

Since that court decision, the SSI rolls for children whose behavior has been deemed to be not age appropriate have skyrocketed quite a bit. About one-third right now of all the children on SSI are *Zebley* children.

What our interest in the inspector general's office would be is determining whether those children should be on the rolls or not. Did they meet the medical qualifications and the other kinds of qualifications or not? If they did, then they ought to be receiving supplemental security income. If they do not, they ought not to be part of it. That is one of the things that we hope to find out.

One of the shortcomings of the program right now, we believe, is that there is no requirement for a medical treatment plan so that when children become eligible for supplemental security income there is not a requirement to develop a medical care plan, which seems incongruous for what the intent of having children eligible for that is.

One of the things that we are going to be looking at, as I mentioned earlier, is what are the other kinds of services that the children were receiving before they became eligible for supplemental security income, and what kinds of services were they getting afterwards. Would the Medicaid records, for example, indicate that they had more intensive services thereafter?

You correctly state that the supplemental security income check does not have to be used for anything in particular other than to ensure that it is to be used for the benefit of the child, and that could give wide latitude to the parents or guardians of those children. We are interested in how that money was used.

Senator BYRD. Have you made any effort to investigate the number of SSI claims that were mentioned in the ABC World News Tonight story?

Mr. MANGANO. No; we have not as yet.

Senator BYRD. Would you intend to follow up on that?

Mr. MANGANO. We can certainly do that.

Senator BYRD. Have you contacted any of the individuals mentioned in the Washington Post article to investigate the claims they are making?

Mr. MANGANO. No; we have not.

Senator BYRD. Could you follow up on that? Do you think it is worthwhile to follow up on that?

Mr. MANGANO. Yes; I think it is.

Senator BYRD. I have one question dealing with the regulations. Was any thought given to the possibility of fraudulent claims when the regulations were written?

Mr. MANGANO. I do not believe so.

Senator BYRD. Do you know whether anything was done to guard against fraud when these regulations were written?

Mr. MANGANO. No; other than just that the regulations specified which children would be eligible and which children would not. So, as I indicated, what our study is going to be looking at is how clear that guidance, was and if the State disability determination agencies, which are responsible for determining the eligibility of the children, carried out their job as it was prescribed by that guidance?

We will find out then whether they have accurately carried out what the regulation states they are supposed to do.

Senator BYRD. I especially call attention to the regulations, and I have inserted them in the record in the interest of time.

As I look over the criteria, however, I will just emphasize one little section.

Adolescents, age 12 to attainment of age 18, functional criteria parallel to those for primary school children. Cognitive, communicative, social, personal behavioral, concentration, persistence, and pace are the measure of severity for this age group.

Testing instruments appropriate for adolescents should be used where indicated. Comparable findings of disruption of social function must consider the capacity to form appropriate, stable, and lasting relationships.

If information is available about cooperative working relationships in school or in part-time or full-time work, or about the ability to work as a member of a group, it should be considered when assessing the child's social and personal behavioral functioning.

Markedly impoverished social contact, isolation, withdrawal, and inappropriate or bizarre behavior under the stress of socializing with others also constitute comparable findings.

Attention deficit, hyperactivity disorders, deficiencies of concentration, persistence or a pace resulting in failure to complete tasks in a timely manner can identify the child who cannot adequately function in primary school because of a mental impairment.

A careful reading of these criteria would lead one to believe that many of them could be easily faked. And has already been implied or even charged here, can be coached by parents who seek to enlarge their family income at the cost to Federal taxpayers.

It seems to me, Mr. Chairman, that one thing we ought to do around here, we ought to sunset many of our authorizing laws, sunset them. We ought to sunset those laws so that Congress will be forced to give its attention, when the time comes to renew those

laws, give its attention to the performance, the cost, whether the program has met expectations, and whether fraud is being committed.

And so we are lax in our duties in this respect. We take bills to the floor, 687 pages—I think one reference was made to such a bill—take them to the floor. Somebody offers a complete substitute. We do not know what is in the substitute. We have not had time to study it. Few people take the time. Most of us are busy doing other committee work for our constituents. So, this is the way we pass these laws.

And later, when we find that they burgeon as to costs and they are filled with considerable waste we are astonished, and it takes the newspapers and the electronic media to bring the facts to the American people's attention. Sunsetting might help.

Thank you, Mr. Chairman.

Senator HARKIN. I agree with you, Mr. Chairman. I think that especially in the area of entitlement we ought to look at sunset legislation, and maybe even look at some of the programs that have been ongoing for some time and start slipping in sunset laws right now on them. I want to thank you particularly for focusing on this issue.

I am equally disturbed Mr. Mangano. I am a little shocked at your response to Senator Byrd's question regarding the situation in Arkansas that came to our attention, where it went from 6 to 17,000 in less than 3 years.

And Chairman Byrd asked you if you had done any investigation of that, and your response was no. I am wondering why not. I would think that this would stick out like a sore thumb, and that you in your capacity as inspector general would be wondering why and how does that compare to other States.

Mr. Mangano, the story on Arkansas came out on May 2. I know that is only a couple weeks ago, but I would think you would be a little more forthcoming in your response that maybe you have not but that you are going to look into it.

Is that a fact? Are you going to look into it?

Mr. MANGANO. Yes; as I indicated in my response, we will look into those cases.

The way we will have to deal with that is to take a look at the individual cases themselves to determine whether the individuals are eligible. The State disability determination offices will have to do that.

If there is an indication of fraud, that is where the Inspector General's Office would get involved. But it would be the ongoing responsibility of the State disability determination service to determine eligibility.

Senator HARKIN. I am just wondering, going from 6 to 17,000 in Arkansas in under 3 years, is that comparable in other States, or could you let me know?

Mr. MANGANO. Yes; there are increases in this program that are pretty astounding. We have had skyrocketing numbers of children added to the rolls just in the last couple of years since that court decision. The money being paid has increased correspondingly.

But we do notice across the country a haphazard increase in eligibility for children.

Senator HARKIN. What is the Social Security Administration doing to look into this? This comes under your purview, Dr. Chater. Are you going to be looking at this? Have you started?

Dr. CHATER. We have been doing many. We have taken many initiatives. For example, in the Arkansas situation, when it was called to our attention that there were crazy checks, as it was called, we sent our Office of Program Integrity Review to Arkansas to actually look at the cases, to actually see what they could find in terms of the evidence to suggest that children were being coached.

The cases were reviewed. We talked with the people who work in those offices. And I have to say to you that there was no evidence found that widespread coaching went on.

Now, that is not to say that there was not a case or two or however many of children who were coached, but we did not find evidence that there was widespread coaching in the State of Arkansas.

I would also like to say that we are very, very concerned about this issue, and we try just as soon as we hear an allegation to investigate, and to redevelop the case, and examine it all over again. It is very, very difficult for our employees and those of the State agencies to make these decisions because, as we have heard today, these are behavioral manifestations. And yes, they are easy to pretend.

On the other hand, the decisions are made over long periods of time. So, it is behavior over time. And we get information from a variety of people including physicians, psychologists, school teachers, and others who have observed the children, so it is the over time evidence that is collected that makes it—it should make it difficult for parents to coach for a one time only situation.

Senator HARKIN. I guess, if I could interrupt, that is why I have a question again about who is qualifying these kids. Let me just read here.

According to the Social Security Administration, to begin on the disability review process a child must present medical documentation of a severe medical or psychological impairment. The impairment must be identical or equivalent to one appearing on a specific list of qualifying impairments, or must significantly interfere, et cetera, et cetera.

That is step one. Step two, the disability examiner must also consider functional information from people who observe the child over a period of time such as parents, social workers, child care providers, clergy, and school personnel.

Third, to make a decision, the disability examiner is required to review all available information about the child's daily functioning.

So, I guess when I read this I wonder when, first of all, they have to have medical documentation who are the doctors who are certifying them. I mean, I have to ask that question too. Why would the doctors certify this? And then the examiner has to interview social workers, teachers, things like that.

Dr. CHATER. The medical evidence, sir, comes from some standardized tests. Intelligence tests are utilized to look at mental retardation, which is much easier, I would add, to document than behavioral problems. But we do give psychological tests, and some of

the health professionals that are involved in providing that evidence are certified clinical psychologists.

And then that is also documented, as you say, with information that talks about how these children are able to function in their everyday life compared to other children of their age. It is a composite of a large number of pieces of evidence. And I have to underline the extreme difficulty our employees have in making these decisions.

Senator HARKIN. Well, maybe we are going to have to figure out some way of delineating it better, or something like that. I look forward to working with you on that.

The Chairman has raised some important issues here.

Senator BYRD. Mr. Chairman, the medical criteria submitted by medical doctors, specialists and so on deals with those children who have physical impairments, and these cases can be carefully documented, evaluated, and decisions made upon them which, I think, do not lend themselves to fraud.

It is the other kind of case in which they are talking about children who do not compare with others of the same age level, and where they have very different criteria which can be faked unlike most of the medical evidence that is submitted if children have leukemia or serious impairment of the sight or heart problems or lung problems.

One final question. I will ask this of Dr. Chater. How much has the cost to the children's SSI disability program grown since 1990?

Dr. CHATER. How much does it cost since 1990? It is approximately \$60 million, I am told. It is currently \$60 million.

Senator HARKIN. \$60 million? If you want to talk about all of SSI, yes, this is the chart over here, Mr. Chairman. It goes from in 1990 a little less than \$15 billion, and now we are up to about \$25 billion; \$13.8 billion to \$25.1 billion. That is all of SSI.

Senator BYRD. Thank you, Mr. Chairman. I hope that the report will be carefully scrutinized by this committee and by other committees of the Congress, and I hope that the awareness level of our colleagues will be raised, especially in the light of this newspaper article and the television report.

Thank you.

Senator HARKIN. Thank you, Mr. Chairman.

We will include in the hearing record at this point a status of reviews of supplemental security income payments to disabled children.

[The information follows:]

STATUS OF REVIEWS OF SUPPLEMENTAL SECURITY INCOME PAYMENTS TO DISABLED CHILDREN

The Office of Inspector General is looking into the participation of children in the Supplemental Security Income [SSI] program. We selected 1992 as the sample year for our review. Three reports will be issued:

- A program profile, including legislative history and concerns brought to our attention by members of Congress. (Draft by 08/23/94.)
- A report on the adequacy of SSA guidance and States' program compliance, including an analysis of allowance and denial cases. (Draft by 09/30/94.)
- A report on the types of medical treatment being received by children for their disabilities under the Medicaid program. (Draft by 10/31/94.)

Report 1: Program profile

Because some of the concerns that we have heard from the public and from Members of Congress focus on the very purpose of child participation in the SSI program, we are reviewing the legislative history of the program. The first report will discuss the following:

- Legislative intent for SSI payments to children.
- Impact of the U.S. Supreme Court decision in *Sullivan v. Zebley*.
- Severity of impairments.
- Financial need and access to other assistance programs.
- Cash payments to representative payees.

Report 2: Program compliance

Primary objectives of our second report include evaluating:

- The adequacy of SSA guidance provided to States for determining whether SSI applicants are disabled.
- States' compliance with this guidance in their allowance and denial determinations, including identification of instances of parental coaching.

We are doing our field work in 10 States. In each State, we have randomly selected a sample of approximately 30 children determined eligible for SSI benefits in 1992 and are reviewing the case files to determine if there is sufficient medical evidence to support the approval. In cases where the evidence is questionable in the eyes of our auditors, we are having SSA experts review the files and provide us their opinions. We are also questioning State personnel to obtain their views on the adequacy of the SSA guidance. We are providing the users of that guidance an opportunity to be heard and to contribute to improvements in the program's administration.

The second report also deals with a sample of denials to determine if the information in the case files supports SSA's denying children SSI benefits. This is a national review involving a statistical sample of 270 children denied benefits in 1992. Again, we are having SSA review questionable cases and provide us with their opinions.

Report 3: Medical treatment

The third report deals with the fact that treatment of the child's disability is not required by law unless the child is under a treatment plan at the time the SSI application is initiated. We will identify treatment being received by the children under the Medicaid program. In particular, we plan to compare treatment received to treatment recommended for children diagnosed as having attention deficit hyperactivity disorders [ADHD].

Senator HARKIN. I just have two other things I want to cover. Dealing with DA&A, drug addiction and alcoholism, I have here a list of the States. Two States, California and Illinois, make up 50 percent—almost 50 percent; 49 percent of all of the case load in the entire United States.

Here is Illinois with 13,119. Yet, you find a State that is comparable in population, Florida, which only have 546; Maryland, 712; and Massachusetts, 1,874. Why would two States account for over one-half of the case load?

Mr. MANGANO. We have talked to officials in the States to try to uncover some of the reasons ourselves. There are a few things. Particularly in California and Illinois there are very strong advocacy groups that are out there trying to get people enrolled that they believe ought to be enrolled.

Some States are telling the individuals applying for general assistance to apply for SSI first before they can become eligible for the State assistance.

The State of Michigan just recently required its general assistance program to send people to SSI first before they can get on general assistance. That State's DA&A population is moving up very quickly. Of course, California claims good weather and higher SSI payments attract people to their rolls.

California has a fairly large supplement that they add to the SSI check, which makes it attractive.

Senator HARKIN. I understand that in California, for example, the Governor has instituted certain processes to get people in California off of general assistance. When they go off of general assistance, where do they go?

Mr. MANGANO. They go to SSI.

Senator HARKIN. They go right there.

Mr. MANGANO. That is correct.

Senator HARKIN. That is exactly what is happening. So, maybe the Governor has learned how to game the system. I should not say that. All the other Governors will be looking at this too, and they will find out too. But that is true.

I want to ask a question about the representative payees here; 60 percent on this chart up here going to relatives, 35 percent to others. There was on this one television show the bar that had all the checks lined up on the bar, which was a representative payee.

It is questionable whether this is the best way to do it. I am wondering if perhaps this chart should not be turned around. Mental and nonmental institutions should get the 60 percent, and social agencies 35 percent, and maybe it just ought to be the mirror image of that perhaps. What say you?

Mr. MANGANO. Well, we have done a lot of work in about the last 3 years on the representative payee issue and have worked very cooperatively with Social Security on it. We are undertaking right now a very large study taking a look at the representative payees and what are they doing in relation to the persons for whom they are accepting the payments.

I can say that on the basis of our earlier work, most representative payees are very responsible persons. They are family members, parents who have children who may be disabled or mentally retarded, other kinds of conditions.

The advantage of having family members as representative payees is that they often have a lot of contact with that beneficiary, and they can maintain that beneficiary over time. They can dole out the money and make sure that the rent is paid, the utilities are paid, and any addition money that is available is given to the recipient over the course of the month.

The advantage of having an organization like a social service agency doing it is that they can become very adept at managing budgets and making sure that people toe the line. The disadvantage is that they do not have a lot of personal contact.

One of the trade-offs that we need to be aware of is that representative payees that are family members do not get paid for that representative payee function, whereas organizations may accept a fee for that service. That fee would have to come from the check, the supplemental security income check.

Family members who are representative payees are doing this in most cases not out of a sense that they are going to be enriched by it, but rather out of responsibility for the family member. If we move in the direction of more institutions, we are going to have to be willing to allow payments to the institutions.

Regarding the example given of the bar, when we did our sample survey about 3 years ago about who the representative payees

were, there are very few examples that would come to that. I believe that the ABC show tried to identify the absolute worst case, and they found it. I do not believe that is the normal case.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I have some more questions for the record that I would submit to both of you, Dr. Chater and Mr. Mangano, and unless you have anything else to add that is it for us today.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AVAILABILITY OF TREATMENT

Question. Currently, over 100,000 substance abusers are on waiting lists to access publicly funded treatment. To what extent is appropriate treatment available for Supplemental Security Income [SSI] recipients?

Answer. SSA's role in administering the treatment referral and monitoring provision of the law is not to determine what kind of treatment is appropriate, but rather to find qualified agencies which are capable of making that determination. Even so, the referral and monitoring process we have used in past years was not systematic enough for us to know whether sufficient treatment services exist for SSI recipients who are disabled by drug addiction and alcoholism [DA&A]. We have, however, made recent improvements in this area.

We have developed a new contract process structured to require each Referral and Monitoring Agency to perform numerous specified tasks that will assure better service to SSI recipients and greater management oversight by SSA of the referral and monitoring process. As a result, we hope to have preliminary information available by the end of the summer concerning SSI recipients who are referred for treatment, including data about treatment availability.

MONITORING AND REFERRAL COSTS

Question. It costs, on average, \$600 to monitor a recipient disabled by drug addiction and alcoholism [DA&A]. What type of services are provided with this funding?

Answer. For the approximately \$600 average cost per case in fiscal year 1994 to refer and monitor each SSI recipient disabled by DA&A, the Referral and Monitoring Agency [RMA] is required by SSA to: review SSA files and conduct face-to-face interviews with each SSI recipient disabled by DA&A; notify the representative payee of the individual disabled by DA&A of all actions occurring in the referral and monitoring process; determine the most effective treatment source and adhere to specific requirements for referring recipients for treatment; ensure the recipient begins treatment activity; monitor the treatment progress of each SSI recipient disabled by DA&A on an ongoing basis (weekly for some period); administer detailed procedures for dealing with instances of treatment refusal and non-compliance, including SSA notification; and assess each SSI recipient disabled by DA&A no later than the 24th month of treatment to determine if treatment should continue and, if appropriate, refer him or her for vocational rehabilitation.

Also, to ensure greater SSA management oversight of the referral and monitoring process, the contracts require RMA's to: maintain an automated control system with complete individual case files, subject to quality review by SSA, for each recipient who is referred by SSA for referral and monitoring services; obtain and verify documentation of treatment from providers; and submit monthly reports to SSA which provide detailed caseload data, including information about recipients who are in noncompliance with treatment requirements.

TYPE OF TREATMENT AVAILABLE

Question. What kinds of treatment programs are Supplemental Security Income [SSI] recipients who are disabled by drug addiction and alcoholism [DA&A] in? Is the type of treatment available appropriate for their needs?

Answer. As I have already indicated, the referral and monitoring process we have used in past years provided little information about the treatment programs, includ-

ing the availability of appropriate treatment or the progress made by recipients disabled by DA&A.

However, I am confident that the newly established uniform contract process will ensure better service, including appropriate treatment, to SSI recipients disabled due to DA&A and will also provide necessary data to allow SSA to provide better management oversight of the referral and monitoring process.

REFERRAL AND MONITORING PROCESS

Question. According to your testimony of February 19, 1994 before the House Ways and Means Subcommittee on Social Security, you "have developed a contract process structured to require each Referral and Monitoring Agency [RMA] contractor to perform numerous specified tasks that will assure both better service to SSI recipients and greater management oversight on SSA's part of the referral and monitoring process."

Outline in detail what these "numerous specified tasks" are and what "greater management oversight" you are providing.

You have recently awarded a major contract to oversee Supplemental Security Income [SSI] recipients disabled by drug addiction and alcoholism [DA&A]. Provide the subcommittee with a summary of the workplan and budget for the contract.

Answer. In collaboration with the Public Health Service's Substance Abuse and Mental Health Services Administration, we have taken major steps to improve referral and monitoring services for SSI recipients disabled by DA&A. We developed a new improved contract which provides specific guidance to RMA's as to how they should operate on a day-to-day basis. These new contracts are currently in place in 34 States and the District of Columbia. We plan to expand these new contracts into the remaining States by the end of this fiscal year.

The specific tasks outlined in the contracts are detailed in a previous question. Some of the required tasks, such as monthly reports to SSA, will help us to provide greater management oversight.

In addition to the specific guidance provided to the RMA's in the new contracts, we have reemphasized to the State Disability Determination Services, in an extensive program directive and periodic reminder items, the need to accurately identify SSI recipients disabled by DA&A. We believe that these oversight efforts will enable us to improve the administration of the DA&A provisions of the law.

Effective January 14, 1994, SSA entered into a 3-year contract with Maximus, Inc., of McLean, Virginia, to refer and monitor recipients disabled by DA&A in 29 States and the District of Columbia. The cost of the contract in fiscal year 1994 is about \$9.7 million.

Attached is an extract from the proposal submitted by Maximus, Inc., describing their general plan of work for implementing a DA&A RMA process.

COST OF REHABILITATION SERVICES

Question. The referral and monitoring process focuses only on treatment, and not on a comprehensive rehabilitation plan. How much funding would be required to provide rehabilitation services to recipients disabled by drug addiction and alcoholism [DA&A]?

Answer. It is very difficult for us to estimate the cost of providing rehabilitation services to recipients disabled by DA&A. State Vocational Rehabilitation Agencies [VRA's] are often reluctant to accept and enroll recipients disabled by DA&A into rehabilitation and employment programs until after they have received treatment and are no longer abusing drugs or alcohol. Thus, we believe that few rehabilitated SSI recipients disabled by DA&A received treatment and recovery services through VRA's.

While we do not have the information necessary to accurately estimate the costs associated with rehabilitating recipients disabled by DA&A, we currently reimburse the State VRA's an average of \$10,500 for providing services to a disability beneficiary who returns to work. We believe that a rehabilitation package for a recipient disabled by DA&A covering treatment, training, rehabilitation, and employment services may cost more than \$10,500 because it would cover a longer period of time and encompass services not generally provided by the State VRA's.

SAMHSA DEMOS

Question. The Social Security Administration [SSA] and the Substance Abuse and Mental Health Services Administration [SAMHSA] are jointly funding demonstration programs designed to test models for improving the management of recipients who are disabled by drug addiction and alcoholism [DA&A].

What are the preliminary results of these demonstrations?

How much funding is in the fiscal year 1994 and 1995 budgets to support these demonstrations? How much more funding could you effectively use to expand this small demonstration program?

Answer. In September 1993, SSA and SAMHSA awarded cooperative agreements for two demonstration projects to continue through September 29, 1996. The demonstration projects are located in the State of Washington and Washtenaw County in Michigan, are jointly monitored by SSA and SAMHSA, and will test alternatives for providing effective treatment and vocational rehabilitation services as well as paying organizational and professional representative payees. Because the demonstration projects are still in their earliest stages of development, we do not yet have any data to report and cannot estimate funding needs for future expansion at this time.

SSA and SAMHSA plan to award one or two additional grants in fiscal year 1994 totalling approximately \$1.3 million. \$1 million is to be provided by SAMHSA and \$300,000 by SSA. SSA has requested \$300,000 for fiscal year 1995 for additional projects.

INCREASED COSTS ANTICIPATED AS A RESULT OF PENDING LEGISLATION

Question. The Senate has passed legislation to put more controls on benefit payments to recipients disabled by drug addiction and alcoholism [DA&A] and expand the representative payee and treatment requirements to Social Security Disability Insurance [SSDI] drug addicts and alcoholics. The House has passed a similar bill. How much additional funding would be required to provide representative payees and referral and monitoring for SSDI recipients?

Answer. Title III of S. 1560, "The Social Security Disability and Rehabilitation Act of 1994," is estimated to cost over \$1 billion in administrative costs for five years. Additional referral and monitoring costs would be approximately \$230 million for disability insurance [DI] beneficiaries who are disabled by DA&A. The House bill, H.R. 4277, is estimated to cost about \$300 million in administrative expenses and \$265 million for referral and monitoring for DI beneficiaries disabled by DA&A and more intensive monitoring of Supplemental Security Income recipients disabled by DA&A. Both bills would require SSA to extend the representative payee requirement to DI beneficiaries whose DA&A is material to a finding of disability. The major difference in the administrative cost estimates is the Senate bill requirement to perform two continuing disability reviews for those disabled by DA&A.

COST OF PENDING LEGISLATION

Question. The House Ways and Means Committee has reported legislation to reform Social Security's disability programs, which CBO estimates will cost \$449 million over the next five years to administer. These would be discretionary outlays, subject to the budget "caps", which are essentially at a freeze level for five years.

How would you carry out these new administrative responsibilities without new money?

Answer. To implement the provisions of H.R. 4277, "The Social Security Administrative Reform Act of 1994", increased funds are needed for Referral and Monitoring Agencies to monitor and test those disabled by drug addiction and alcoholism [DA&A], and additional funds are needed for SSA's principle administrative expense account, the Limitation on Administrative Expenses.

Without additional administrative expenses, SSA would not be able to implement all of the provisions of H.R. 4277, without the further deterioration in service levels for some of our other workloads. However, the legislation could be implemented gradually, starting with the Supplemental Security Income provisions for recipients disabled by DA&A, and then extended to new Disability Insurance beneficiaries on the rolls and to continuing disability reviews, as funds become available.

PROJECTED INCREASE IN THE NUMBER OF RECIPIENTS DISABLED BY DRUG ADDICTION AND ALCOHOLISM

Question. The Social Security Administration predicts that many more disabled individuals will be identified as disabled by DA&A by Disability Determination Services [DDS's] in States that have active Referral and Monitoring Agencies [RMA's]. How much additional fiscal year 1995 funding would SSA need under current law for RMA's to monitor your latest projection of recipients disabled by DA&A on the rolls?

Answer. SSA's fiscal year 1995 budget assumed that the RMA's will monitor about 39,500 recipients disabled by DA&A under the improved referral and monitor-

ing process in fiscal year 1994 and about 69,000 recipients disabled by DA&A in fiscal year 1995. Over the same period, funding requested for RMA's to monitor recipients disabled by DA&A will increase from \$20 million in fiscal year 1994 to \$36 million in fiscal year 1995.

Since we prepared the fiscal year 1995 estimate, recently revised projections indicate that more persons disabled by DA&A will need referral and monitoring. SSA's program estimators now have projected that the number of recipients disabled by DA&A on the SSI rolls at the end of fiscal year 1994 and fiscal year 1995 will be 102,000 and 135,000.

Actual experience with the new referral and monitoring contracts indicates that the actual cost per case in fiscal year 1994 is about \$600. The average cost per case in fiscal year 1995 is estimated to be about \$630, rather than the \$525 cost per case projected earlier.

Current law requires the Secretary to provide for monitoring and testing of all individuals who are receiving benefits under the DA&A provisions. To provide for mandatory testing in fiscal year 1995 (e.g., provide for an average of four substance abuse tests per year) would increase the average cost per case by \$180 to \$810.

For RMA's to monitor most of the estimated 135,000 recipients disabled by DA&A expected to be on the rolls at the end of fiscal year 1995, including mandatory testing, SSA would need \$109 million—an additional \$73 million above the current request.

RMA contracts are usually funded for a 12-month period. Since these contracts are let throughout the year, part of the funding may cover services received in the following fiscal year.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

Question. Does the OIG have recommendations on how to improve regulations on SSI disability payments to children?

Answer. The OIG will be issuing three reports on the participation of children in the SSI program, and will be recommending improvements in the program regulations and guidelines.

One of our recommendations is for SSA to begin continuing disability reviews [CDR] of children receiving SSI benefits to ensure that they remain eligible for the benefits. The CDR's on children are especially needed since the "Sullivan v. Zebley" Supreme Court decision essentially required SSA to conduct individualized functional assessments of children whose impairment is not of equal severity to an impairment on the medical listing of impairments. Reviews performed by SSA and the OIG clearly indicate that the most significant weaknesses in the medical eligibility determination process are with allowed claims and the interpretation of guidelines dealing with the individualized functional assessment of a child's ability to function in an age-appropriate manner.

In our opinion, some of SSA's guidelines are subjective and lend themselves to interpretation. The SSA has recently taken several steps to improve the clarity of its guidelines for the individualized functional assessments. We believe SSA's recent actions should help States' Disability Determination Services make more accurate medical eligibility determination decisions, and we will make additional recommendations to SSA to further improve the medical eligibility determination process.

Question. Does the OIG have recommendations for any changes in the law that may be required to make sure that those who are not truly disabled do not receive the benefit?

Answer. The OIG does not, at this time, plan to recommend changes to the SSI statute. We do, however, support the establishment of a Commission on the Evaluation of Disability in Children as described in the conference agreement for H.R. 4277, the Social Security Independence and Program Improvements Act of 1994. The Commission would be tasked with studying several aspects of the SSI program for children with disabilities.

The work of the Commission could result in future changes to the SSI statute, particularly with regard to the individualized functional assessment of children and to the intended outcome of the program as it relates to children.

Functional Assessment.—The use of an individualized functional assessment of a child's ability to function in an age-appropriate manner as the basis for SSI eligibility is the focus of concerns that we have received from members of Congress, teachers, school administrators, psychologists, States' Disability Determination Services employees, and others. They are concerned that children with impairments, such as a learning disability or an emotional problem, which might interfere to some

degree with school function but will not prevent them from becoming self-supporting adults are being determined eligible for SSI benefits. Generally, States' Disability Determination Services determine children with these types of impairments eligible on the basis of an individualized functional assessment of their ability to function in an age-appropriate manner.

The "Sullivan v. Zebley" Supreme Court decision, in effect, forced SSA to institute these assessments of children whose impairments are not of equal severity to impairments on the medical listings of impairments. As mentioned in response to a previous question, it is these individualized functional assessments that cause most of the eligibility determination decision errors detected by the SSA and OIG reviews. If determining a child's medical eligibility for SSI benefits based on his or her ability to act in an age-appropriate manner was not intended by Congress or found unsuitable by the Commission, legislation may be in order to redefine the definition of disability as it applies to children.

Congressional intent.—If the congressional intent of the SSI program was to provide cash assistance to children with disabilities, as suggested by the SSI statute, the program basically achieves that purpose. If the congressional intent of the SSI program was not only to provide cash assistance to children with disabilities but to help these children become self-supporting adults, as suggested by House Report No. 92-231 dated May 26, 1971, the program achievements are less clear. Neither the SSI statute nor program regulations require that SSI payments be used solely for any special needs of children with disabilities. In fact, there is no requirement that children undergo a treatment plan aimed at helping them overcome their impairments, unless the children are under such a plan at the time of SSI application. Legislation may be required to ensure that children receive the treatment needed to overcome their impairments to the extent possible.

Question. Has the OIG investigated claims of children being coached on how to appear to be disabled, giving special attention to coaching by parents?

Answer. The OIG has reviewed 300 allowed cases in 10 States, and 270 denied cases nationwide. We did not detect coaching to be a problem. We did, however, interview Dr. Nora Cook Porter who was the source of the allegations in the Washington Post article of February 4, 1994. We obtained from her information on cases which she believes should not have been determined eligible for SSI benefits. We have provided these cases to SSA for review, and will follow-up with SSA to determine their resolution.

The SSA has conducted a review of 617 SSI disability decisions and did not find widespread coaching abuse. It found evidence of coaching or malingering (performing below actual ability) in 3 of 325 allowances (about 1 percent) and 10 of 292 denials (about 3.4 percent), or less than 2 percent of the cases reviewed. This is a significant finding since SSA picked high risk cases where coaching could have been expected to occur.

The SSA also conducted an extensive review in Arkansas and found no widespread coaching. The United States General Accounting Office is currently conducting a review in Arkansas of coaching allegations.

Regardless of how widespread the problem of coaching is, to the extent that it occurs, it erodes public confidence in the SSI program. We believe SSA should revise its guidelines to require States' Disability Determination Services to ask school authorities and medical professionals, including consultative examiners, to provide their comments relative to coaching or child malingering on documents that they provide to the States during the eligibility determination process.

Question. Is it appropriate to provide cash payments to the parents of children when those children are residing in a home where the parents or guardians are abusive, alcoholic or drug addicted?

Answer. We agree that it makes little sense to allow cash payments to be directed to individuals who have demonstrated the inability to function within the bounds of societal norms.

SSI is currently developing an automated representative payee system that should enhance its ability to insure that individual's currently receiving payments on the basis of drug or alcohol addiction are not selected as payees for other individuals. Since the system has not yet been fully implemented, we have not reviewed its effectiveness.

With respect to abusive situations, the SSA becomes aware of such situations if a third party, either the State child protective services, a foster parent, or someone else notifies SSA that the child has been removed from a parent's custody. In such cases, SSA would investigate the parent's continued suitability to serve as a representative payee.

We are exploring the feasibility of conducting a future study that will compare SSA records for child beneficiaries and available data from State and local agencies

pertaining to children removed from abusive situations and placed in foster care. The thrust of our analysis would be to determine if existing linkages between SSA and the other agencies provide adequate assurance that payments for children removed from abusive situations are directed to the appropriate care providers.

We believe that parents with problems such as those mentioned should be identified wherever possible, and that SSA should follow up on them to ensure that the parent or guardian is a fit representative payee. We are obtaining information in our 10-State study as to whether Disability Determination Services identify problems of this nature with parents or guardians during their medical eligibility determination reviews and if and how they report these problems to SSA.

Indications are that information which may affect the suitability of a person to be a representative payee is obtained but is not being specifically reported to SSA. Instead, the information is annotated in the case files, which are generally voluminous, and the files are routinely returned to SSA. The SSA could require that information affecting the suitability of a representative payee be "flagged" for its review.

Question. Is it feasible to provide vouchers instead of cash?

Answer. Whether to provide assistance by cash payments or through a voucher system is a policy decision to be made by Congress, one that relates, in our opinion, directly to the purpose of the SSI payments made on behalf of children with disabilities.

If congressional intent is to provide cash assistance to poor children with disabilities, one could argue against a voucher system. If the congressional intent is to provide assistance for the treatment of a child's impairment, a voucher system is one method for doing so. It should reduce the risk of abuse since cash payments would no longer be available to representative payees, and should help ensure that children with disabilities receive treatment for their impairment. The cost of implementing a voucher system would have to be studied carefully.

Question. What is the extent of fraudulent activity in the children's disability program?

Answer. Neither SSA's review nor our review in 10 States has identified widespread fraud or abuse in the SSI program for children with disabilities. Both reviews have determined, however, that States' Disability Determination Services are making errors in their determination decisions. The SSA has concluded that States more frequently misinterpret guidelines associated with children with mental impairments that are usually manifested by behavior or learning dysfunction, or both, and who have been determined eligible based on an individualized functional assessment. The SSA has labeled these cases as high risk. We agree with this assessment.

Our review showed, however, that SSA's computerized systems did not specifically identify these high risk cases. In many cases, States' Disability Determination Services categorized children with behavior or learning impairments as being mentally retarded, a diagnosis which is identified in SSA's computerized systems.

Without computerized data, it will be more difficult for SSA to determine the number of the high risk cases in the SSI population, and to focus continuing disability reviews on this segment. The SSA has plans to refine its identification of diagnoses so that information on learning and behavior impairments will be computerized in the future.

Question. Can you now provide a follow-up on allegations of improper claims and coaching in the State of Arkansas.

Answer. During the May 13 hearing, the Commissioner of Social Security explained to Senator Harkin that, when the allegation of parental coaching in Arkansas was called to their attention, SSA sent their Office of Program Integrity Review to Arkansas to actually look at the cases to see what they could find in terms of evidence to suggest that children were being coached. The Commissioner stated that, after reviewing cases and talking with the people who work in those offices, SSA concluded there is no widespread coaching in Arkansas. Because SSA had already expended considerable resources checking the Arkansas cases specifically, we decided to continue our work which had already begun in other States, rather than to duplicate SSA's effort in Arkansas. We believe the actions taken by SSA in response to its internal review, and the recommendations that we will make in our review, if implemented by SSA, will improve the administration of the SSI program nationwide, including the Arkansas program.

QUESTIONS SUBMITTED BY SENATOR HARRY REID

Question. Please discuss counterfeit SSN cards used by illegal aliens.

Answer. The Office of Inspector General [OIG] has been concerned about fraud and abuse involving the Social Security number [SSN], and has conducted numerous

reviews and criminal investigations involving these issues. Most of our reviews have focused on improved management and controls over the issuance of Social Security number cards. One of our inspections, Social Security Numbers for Noncitizens, addressed the problem of issuance of SSN's to aliens. To enhance the integrity of this process and insure that only those noncitizens authorized to have a SSN receive one, we recommended that the Immigration and Naturalization Service have a role in enumerating aliens as they enter the U.S. Though both SSA and the INS agreed in principle with us, the INS advised that it cannot commit resources to this effort.

With respect to widespread SSN abuses currently taking place, it is not clear that the suggestions for an improved SSN card would curtail these abuses. For example, two suggestions, displaying a photograph and fingerprints and identifying information may better relate a specific card to the bearer of that card, but they would not prevent counterfeiting. Similarly, a third suggestion, to incorporate encoded data, may make it more difficult to counterfeit cards but, to be effective, would require a much more sophisticated system for users to read the encoded data and validate its accuracy with SSA.

The issue of displaying the SSN holder's photo on the card also presents special problems. An individual's physical appearance changes significantly during their lifetime, so periodic reissuance of the card to display an updated photo would be necessary. This is especially true in cases where SSN's are issued to infants—and SSA is currently issuing nearly 3 million SSN's annually through its enumeration at birth project.

If the proposed suggestions for an improved SSN card were adopted, effective implementation would seemingly require reissuance of all SSN cards. In recent testimony, the Social Security Administration estimated that such reissuance would cost \$2.5 billion and would require an additional 8,000 employees.

The OIG is highly supportive of efforts to reduce fraud and abuse involving Social Security numbers. It is not clear to us, however, that the proposed changes will have the desired impact. We believe that much more work needs to be done to insure that appropriate and cost-effective measures are taken to minimize the risk of fraud. We will be happy to work with your staff to identify appropriate steps that can be taken to deal with these problems that we believe extend well beyond illegal immigration.

Question. What effect will SSA's restructured disability claims process system have on fraud and abuse?

Answer. We in the Office of Inspector General share your concern about the potential for fraud and abuse in the disability program. Allowing claimants to obtain and provide their own medical evidence of record may have some major benefits in terms of reducing processing time for adjudication of the claim. However, as you note, such action is not without a commensurate increase in the risk of fraud. We previously advised SSA of our concerns in a January 1988 report entitled "Integrity of Medical Evidence in Disability Determinations." We will again share our concerns regarding the risks of altered or fabricated evidence in our comments to SSA's Disability Reengineering Team.

Overall, we support the SSA reengineering team's position that the current disability process is broken and requires a drastic change if SSA is to meet its obligations for world class service to the public. The Disability Process Redesign is a major first step toward achieving this goal. We intend to work with SSA in providing whatever assistance is necessary in order to ensure that the potential for fraud and abuse is minimized, if not eliminated.

As we understand the proposal for the Disability Process Redesign, the Disability Claim Manager will be responsible for handling the claim and will be the point of contact for the claimant. This does not mean that the Disability Claim Manager will be making the decision without the advice of expert medical consultation. While the operational aspects of the proposal have not been formulated, the process, as it has been explained to us, will involve a team approach seeking the expertise of other individuals in the decision. The Disability Claim Manager will be the focal point at the initial claim level, assisted by technical and medical support staff.

Question. SSI Benefits to Drug Addicts and Alcoholics: (a) What steps has SSA taken to more effectively enforce the cessation of benefits if a beneficiary is not complying with the treatment requirements?

Answer. We understand that SSA is in the process of expanding and intensifying its referral and monitoring of DA&A treatment by contracting with Referral and Monitoring [RMA] agencies in all States. Under this process, SSA will require that RMA's perform specific tasks concerning drug addicts and alcoholics. These tasks include a requirement that the RMA report to SSA any failure of a DA&A recipient to comply with treatment requirements.

Question. (b) Are cash payments appropriate? What effect might a voucher type system have on the abuse of cash benefits?

Answer. Whether to provide assistance by cash payments or through a voucher system is a policy decision to be made by Congress. However, preliminary data from current OIG reviews show that the abuse of cash payments is not as big a problem as is being portrayed in the media—most benefits are being properly managed by the representative payees.

Nevertheless, substituting a voucher system for cash payments may eliminate some abuse. The cost of doing so could be prohibitive.

Question. (c) What type of screening system is in place for reviewing the background of a designated payee?

Answer. Although SSA requires a considerable amount of personal, financial, and living arrangement data from applicants to be representative payees, our understanding of SSA procedures is that they typically do not verify the data provided. SSA is conducting a study, which was required by the Omnibus Budget Reconciliation Act of 1990, to determine the feasibility of identifying representative payee applicants with prior criminal convictions, and under what circumstances they should be allowed to serve as representative payees. We understand that SSA will soon report the results of that study to the Congress.

Question. (d) Do you think that the requirements recently passed by the Senate will help to alleviate some of the fraud associated with this type of benefit?

Answer. The recent requirements, such as time-limited payments and progressive penalties, could be effective in eliminating some of the abuse of the program. Discussions with treatment providers indicate that such requirements could provide necessary incentives for genuine compliance with treatment.

Question. (e) What areas do you think could still use some improvement?

Answer. The OIG is actively reviewing a number of areas involving drug addict and alcoholic issues. These reviews are focused on management control over the monitoring and treatment of drug addicts and alcoholics. Final reports should be available by August 1994, and we will be happy to share them at that time.

It is clear from our past and current work in this area that treatment for substance addiction has been subordinated by the demands to make disability decisions and issue payments. We firmly believe the opposite emphasis is needed. We are hopeful that SSA's current emphasis on its responsibilities for referring and monitoring the treatment of drug addicts and alcoholics will reverse this trend. We will continue to monitor SSA's progress in this area.

Question. I have become very concerned about the prevalence of health care fraud and abuse. It is estimated that 10 percent of every dollar spend on health care goes to fraud and abuse. According to the General Accounting Office, health care fraud and abuse cost the American taxpayer as much as \$80 billion each year. What initiatives have HHS and the Health Care Financing Administration [HCFA] implemented to reduce fraud and abuse of federally funded programs?

Answer. Created in 1976, the Office of Inspector General [OIG] is statutorily charged with protecting the integrity of departmental programs, as well as promoting their economy, efficiency and effectiveness. We meet our challenge through a comprehensive program of audits, program evaluations, and investigations. The activities of our office consist of a multi-faceted approach to improving the management of the Department and protecting the programs and beneficiaries from fraud, waste, and abuse.

In addition to the activities of the OIG, HCFA, as administrator of the Medicare program, plays a significant role in combatting fraud and abuse. The OIG works closely with HCFA and the Medicare contractors that process Medicare claims and perform payment safeguard functions. Payment safeguard activities are designed to control costs and over-utilization, and detect fraud. These activities include: (1) medical/utilization review, (2) benefits integrity, (3) provider audits, and (4) Medicare secondary payer activities.

As a result of our recommendations over the last several years, HCFA initiated a broad effort to get the Medicare contractors to take a more active role in detecting, developing and referring potential fraud cases to the OIG. Among the changes that HCFA implemented was the creation of fraud units within most Medicare contractors. To date, 65 Medicare contractor fraud units have been established, including units for the four regional claim processing contractors for durable medical equipment. The Medicare contractor fraud units are funded at approximately \$32 million and employ about 450 people. We believe that their efforts will significantly increase the quality of case referrals to our office from the contractors.

In addition, the OIG and the State Medicaid fraud control units [MFCU's] have concurrent investigative authority in the Medicaid program and conduct joint inves-

tigations. The MFCU's, supported largely (75-90 percent) by Federal dollars, devote approximately 1,200 personnel to investigating Medicaid fraud.

Question. What is the budgetary amount dedicated to these initiatives?

Answer. The OIG has an annual budget of approximately \$100 million. HCFA program safeguard functions are currently funded at approximately \$398 million. Federal funding for State Medicaid Fraud Control Units is currently \$69 million.

Question. What valiative results have been shown?

Answer. In fiscal year 1993, our office returned \$61 for every dollar appropriated to us. These accomplishments are reported to Congress in our Semiannual Reports to the Congress. The "savings" generated by our office are comprised of savings, fines, restitutions, judgements, settlements, recoveries, and receivables.

The vast majority of the savings generated by our office are in the form of budgetary savings or "funds put to better use." One of the mandated responsibilities of our office is to recommend actions that can be taken by the Congress and/or the Administration which will result in greater economy and efficiency. We maintain a listing of all our significant unimplemented recommendations which would result in savings or cost-avoidances and include this information in our Semiannual Report to the Congress. We also publish it annually in our "Cost-Savers Handbook," typically referred to as the "Red Book." When these recommendations are enacted, we report them as savings in our semiannual report. We typically report savings estimated by the Congressional Budget Office for legislative changes.

Based on our audit and inspection activity, we also make recommendations for the recovery of questioned and unsupported costs or charges to the Department's programs. These activities result in moneys being recouped by the Government.

Finally, our investigative activities result in court-ordered fines, restitutions, and judgements, as well as settlements and civil monetary penalties imposed by our office.

The Medicare contractor payment safeguard activities are reported to save about \$14 for each dollar spent.

The MFCU's reported 628 convictions in fiscal year 1993 with total recoveries of over \$41.6 million. Approximately 25 percent of their caseloads involve patient abuse allegations, for which there is no monetary recovery.

Question. Is it possible for you and your staff to pinpoint the areas where the most fraud and abuse occur?

Answer. We can safely state that health care fraud permeates the entire system. It can be found in all areas of the country and is committed by every type of provider. We investigate cases ranging from simple false claims to complex schemes involving large groups of people.

Billing for services not rendered continues to be the most common type of fraud committed against the Medicare and Medicaid programs. Frequently, our investigations also involve providers and suppliers who "game" the programs by unbundling and upcoding charges. We also have become increasingly involved in investigating alleged violations of the anti-kickback statute which prohibits the payment or receipt of anything of value as an inducement for the referral of Medicare or Medicaid business. Other scams investigated by our office include charging for generic drugs at brand-name prices, and selling fraudulent or worthless medical products.

While these types of fraudulent activity can permeate all aspects of the health care system, we have devoted significant resources to areas that appear rife with abuse. These areas include home health agencies, psychiatric clinics, clinical laboratories, home infusion, and durable medical equipment.

Question. It is estimated that Medicare and Medicaid fraud consumes \$80 billion a year. Under President Clinton's plan for health care reform, several provisions are aimed at reducing fraud. What will be the impact of these measures? Do they go far enough? What would be a reasonable percentage of reduction in fraud if these provisions were implemented?

Answer. We believe that any health care reform plan should have strong fraud and abuse provisions. We believe that three major problems should be addressed.

First, the health care reimbursement system should be simplified. Currently, there are so many different billing forms, medical coding conventions, provider and patient identification systems, rules of coverage, payment methodologies, and claims processors that it is extremely difficult to detect and deter sophisticated fraud or abuse.

Second, statutes should be strengthened to protect citizens from those who defraud the health care delivery system. This action would mean not only improving authorities that currently apply to the Medicare and Medicaid programs, but also establishing authorities that can be used to combat fraud perpetrated against private health plans. Currently, administrative actions such as CMP's and exclusions,

as well as anti-kickback provisions, do not apply beyond the Medicare and Medicaid programs.

Third, we support the establishment of a new funding mechanism for more aggressive enforcement in the health system. We believe it is appropriate to have those who defraud the system pay for greater enforcement. Several reform plans that have been proposed would establish a special account to "recycle" moneys recovered from those who defraud the health care system. Deposits into the account could include money recovered in health care cases such as criminal fines, civil penalties and damages in cases brought under the False Claims Act, and administrative penalties and assessments. Of course, restitution would continue to be made to the programs and plans which suffered the losses.

We believe that the Health Security Act contains provisions that adequately address these three areas. If enacted these provisions should enhance the ability to combat health care fraud. However, we do not have the ability to estimate how much fraud would be eliminated as a result of enactment of these provisions. In fact, there is currently no reliable way to estimate the amount of fraud in the health care system. The \$80 billion fraud estimate comes from a GAO report which stated that 10 percent of health care was fraud. This "estimate" represented opinions of individuals rather than an empirical estimate. We do know, however, that wherever we look for fraud we find it. And our health care investigative cases result in savings of \$18 for every dollar spent. Therefore, depending on the resources expended, the savings could be quite large.

Question. In your testimony before this Subcommittee a few week ago, you indicated that one of the major problems in identifying fraud and abuse was that you have over 4 billion claims a year covering over 2 million different providers. You state that the payers use different claim forms, payment methods and coding procedures and that a lack of resources is a problem. Under health care reform, it is hopeful that we will be able to streamline that administrative burden of claims by creating relatively few uniform claims forms. Will Medicare also be making adjustments?

Answer. Medicare and the Department have made significant efforts to streamline and standardize the claims processing systems. Some of these actions include:

- Increased use of "shared" claims processing software and processing facilities among the Medicare contractors—from unique processing at each contractor to use of 14 shared systems at about 60 processing sites. Issuance of "core" requirements for all shared systems—covering both parts A and B of the Medicare program.
- Implementation of the Common Working File [CWF] system to standardize prepayment authorization of Medicare claims nationwide.
- Consolidation of specialty claims processing (i.e., home health agency bills and durable medical equipment claims) at regional contractors.
- Initiation of the Medicare Transaction System [MTS] project to replace most Medicare processing now done through shared systems and CWF.
- Cooperative efforts with the private sector (Workgroup on Electronic Data Interchange, or WEDI) and nationwide standards setting organizations (e.g., American National Standards Institute, or ANSI) to adopt standard health care transaction formats and data communications protocols on an industry-wide basis.
- Streamlining Part B claims submission procedures and standardizing electronic claims formats nationwide in the Medicare program. Also, changes in Medicare law to permit earlier payment for electronically submitted claims. And, additional emphasis at carriers on furnishing technical assistance to physicians/suppliers to promote electronic billing and payment using standardized national formats.

We would anticipate that these initiatives would continue and potentially increase with the advent of health care reform.

Question. Another suggestion you made was for an All-Payer Health Care Fraud and Abuse Control Account. Tell me how this would work.

Answer. The Health Security Act establishes a health care fraud and abuse control account that would receive Federal moneys collected from health care cases that would not otherwise be returned to the program that suffered the loss. Funds deposited in this account would include criminal fines imposed in cases involving a Federal health care offense, civil penalties and damages imposed in health care cases under the False Claims Act (other than funds awarded to a relator or for restitution), administrative penalties and assessments in health care cases (other than funds returned to original payers, such as the Medicare Trust Fund or the States), and amounts resulting from the forfeiture of property by reason of a Federal health care offense.

The fraud account will be controlled jointly by the Department of Justice [DOJ] and the Department of Health and Human Services [HHS] and funds should be available to all entities with a role in combatting health care fraud and abuse.

We support this new funding mechanism for more aggressive enforcement in the health system. We believe it is appropriate to have those who defraud the system pay for greater enforcement.

Question. A Nevada constituent had told me of many abuses in the durable medical equipment industry due to billing codes that she says are wide open, leaving too much room for some providers to take advantage of higher reimbursements by upcoding. What assurances do we have that appropriate payments are made for equipment? What reviews are in place to see that the equipment is needed and actually used?

Answer. Many abuses have been documented in the DME area for many years now. As a result, many statutory changes have been enacted and HCFA has undertaken significant reforms. These reforms include consolidating the claims processing for DME into four regional carriers, changing point-of-sale rules, and mandating that suppliers apply for provider numbers and meet certain standards. We believe that these reforms will significantly reduce the fraud and abuse we have seen in this area.

The four regional carriers responsible for processing DME claims have responsibility for ensuring that DME equipment and services meet Medicare rules and regulations. This is accomplished through their payment safeguard activities. In addition, the OIG continues to conduct reviews in this area and to notify HCFA of program vulnerabilities.

Question. My constituent had informed me that your office has responded to many of her reports of fraud and abuse. She believes that tighter controls on assigning provider numbers will assist with identifying companies which submit multiple claims. Has this issue been investigated? Many companies employ third-party billing. What is being done to more appropriately detect fraud perpetrated through third-party billing?

Answer. A number of years ago, the OIG studied the issue of how provider numbers were issued under the Medicare program. In the area of DME there were little, if any, controls over the issuance of these numbers. As a result of abuses in this area, as part of its DME reforms, HCFA has required all DME suppliers to apply for and receive new provider numbers. As part of the application process, suppliers have to submit ownership information and information regarding sanctions. We believe that these reforms will correct many of the abuses we have found in this area, including suppliers using multiple provider numbers to submit duplicate claims to the program. We do plan to review the National Supplier Clearinghouse to assess its effectiveness.

Fraud perpetrated by third-party billing is detected by the payment safeguard activities of the Medicare contractors. These entities are responsible for determining that a service was provided and covered by Medicare and reimbursed according to program rules.

Question. It has been brought to my attention that it takes up to four years to prosecute someone who perpetrates Medicare fraud. What is an appropriate and reasonable length of investigation of a Medicare fraud case based on the number of staff you have available?

Answer. The OIG currently has approximately 2,800 open cases (all cases). About half are less than a year old and 75 percent are less than 2 years old. Only 10 percent of these cases are more than 36 months old. Health care cases are time-consuming to develop and prosecute. The increased emphasis being placed on health care fraud at the Department of Justice has reduced the time it takes to conclude a case. Staff reductions in the OIG have increased the time it takes to conclude cases and has also necessitated that we refer cases to the Federal Bureau of Investigation.

Question. The State of Nevada is preparing to implement a managed care system for Medicaid. Have you seen any reduction in fraud and abuse as a result of your managed care Medicare Program? What examples or types of fraud and abuse have arisen under managed care?

Answer. The types of fraud and abuse that occur in managed care plans are very different than those that exist under fee-for-service plans. In fee-for-service plans, there is an incentive to order (or claim) more services because the provision of additional services typically increases the provider's revenue. Under managed care plans that are reimbursed based on a flat, capitated payment, there is an incentive to minimize the provision of services as additional services do not result in additional payments to the provider. Under such a system, there is an incentive to "skim" patients—or discourage the enrollment of (or actually disenroll) unhealthy patients or

patients in high risk groups. Further, there is an incentive to deny patients expensive care even when it is medically indicated. Reform to the health system should ensure that there are adequate safeguards against such abuses.

QUESTIONS SUBMITTED BY SENATOR KOHL

Question. The Office of Inspector General [OIG] was asked to determine how much the Federal Government loses every year because "unqualified" children get SSI. We understand the audit is not complete, but could you provide a ballpark figure at this time?

Answer. One of our audit objectives is to determine the extent of Disability Determination Services' [DDS] compliance with SSA guidelines when making medical determination decisions in both allowed and denied cases. A draft report related to this objective will be issued on or about October 1, 1994.

Preliminary results indicate that:

- 6 percent of the allowed cases reviewed should have been denied and less than 1 percent of the denied cases should have been allowed.
- 16.4 Percent of the allowed cases reviewed and less than 1 percent of the denied cases should not have been adjudicated without the States first obtaining additional evidence to support their medical determination decisions.

Question. As part of OIG audit work, have you determined how much would be saved if SSA got more money for more frequent reviews of individual SSI cases?

Answer. The OIG will issue a report in the near future which deals broadly with savings which could be realized if Continuing Disability Reviews were increased for disability beneficiaries in general. Regarding SSI children specifically, we have examined a concern that children are being determined eligible for SSI benefits who have impairments that might interfere to some degree with school functioning but may not prevent them from earning a living as adults. We found that:

- There is no requirement that SSA consider the child's potential to earn a living;
- Predicting the potential of is children difficult because of variables including parental roles, the nature and timeliness of treatment, and age; and
- An estimated 86 percent (104,713) of the 124,639 children included in our audit universe were determined by the States to have non-permanent impairments.

We recommended that SSA develop a continuing disability review profile for impairments in children that are most likely to improve over time.

Question. When will OIG work on SSI payments to children be released?

Answer. We selected 1992 as the sample year for our review of SSI children with disabilities. Three reports will be issued:

- A program profile, including legislative history and concerns brought to our attention by members of Congress. (A draft was issued at the end of August.)
- A report on the adequacy of SSA guidance and States' program compliance, including an analysis of allowance and denial cases. (Draft by 09/30/94.)
- A report on the types of medical treatment being received by children for their disabilities under the Medicaid program. (Draft by 10/31/94.)

Final reports will be available to the public about 60 days after each draft is issued. The interim period is for departmental comment.

Question. When an SSI recipient turns 18, he or she is automatically placed on the adult SSI rolls regardless of whether a review is conducted. Do you have any estimates on the savings resulting from a mandatory review of an SSI recipient's case when he or she turns 18? If not, can you provide that information?

Answer. The Social Security Administrative Reform Act of 1994 requires SSA to increase its reviews of the eligibility of children at age 18. SSA will report to the Congress after implementing this provision. Their analysis should show whether increased eligibility reviews result in substantial program savings.

Question. Recent reports indicate that alcoholics and drug addicts have been using their SSI benefits to feed their bad habits rather than pay for the treatment they need. SSI was established to help support those who cannot support themselves. It was never intended to support the habits of drug or alcohol addiction. In an attempt to return the SSI program to its intended and worthy purpose, Senators Cohen and Kohl introduced a bill which would (1) ensure that SSI payments go to third parties who are responsible; and (2) requires beneficiaries to get treatment for their drug and alcohol problems. Would such reforms eliminate the abuses of SSI by some drug addicts and alcoholics?

Answer. Regarding responsible representative payees, the OIG issued a final report in June 1994, *Demographics of Beneficiaries with Representative Payees: SSI Drug Addicts and Alcoholics*. We found that the types of payees and custody arrangements for drug addicts and alcoholics [DA&A] vary widely. While more than

half of payees are relatives, one-third are non-relatives that are coded on SSA's system as "other." Payees coded "other" include, but are not limited to friends, acquaintances, and professionals such as attorneys. We believe these payees may be at higher risk of misusing benefits than parents, other relatives, or institutions. Additional OIG work on representative payee issues is ongoing. We are finding that overall most payees of all types actively manage their recipients' funds. That is, they pay major bills like rent and disburse the remainder in small amounts over the month. Relatives and other individual payees are more involved than organizational payees in the recipients' lives. In general, they have known them longer and are more likely to see them daily.

Regarding enforcing treatment requirements, we issued a report in 1991 which recommended that SSA clearly define treatment and successful rehabilitation, correct data that identifies DA&As and their treatment status, and strengthen the monitoring system. In response to our recommendations SSA began to take significant action to increase monitoring. This effort will be further enhanced as a result of this year's legislation. Our current work indicates that about one-third of DA&A recipients are in treatment. Many (39 percent) of those recipients not currently in treatment were reportedly once in treatment. The more common reasons offered for failing to complete treatment include not having money for treatment (despite being Medicaid eligible), lacking transportation to the program site, or not liking the people at the program.

Question. In early May, the House Ways and Means Committee passed a bill that requires HHS to establish a Commission to evaluate disability in children. Do you think such a Commission could help clarify how we can make sure that deserving children get the assistance they need while ensuring against abuses of the system?

Answer. The requirement for such a Commission has now been enacted, and we support it strongly. The OIG contributed to the dialog about the scope of the Commission's charge, and feel that all the significant issues will be covered in the scope of its review. We have offered our expertise to the implementation of this effort and look forward to its outcome.

Question. Will you be better able to reduce the incidence of health care fraud if we pass a law to: (1) extend existing health care fraud laws to cover private insurance in addition to Medicare and Medicaid; (2) increase criminal penalties for health care fraud; and (3) increase funding by \$100 million over five years, as my bill does?

Answer. If the Congress were to enact these three provisions we would be more effective at combatting health care fraud.

We have stated numerous times that we believe that three major problems must be addressed if we are to reduce fraud and abuse in our health care system. First, the basic structure of the current health care system needs to be simplified. The health care system is vulnerable because of its size, complexity, and the fragmentation of processes and information systems used to administer benefits.

Second, the lack of resources to identify waste and combat fraud and abuse is a major problem because it allows harmful practices to continue and defrauders and abusers to escape detection and prosecution. The limited resources available are inadequate to address sophisticated and complex schemes that arise each day to defraud and abuse health care programs.

Third, several statutory improvements could be made to protect citizens and their health care plans from unscrupulous providers. While we believe that we have been successful in combatting fraud and abuse in the Medicare and Medicaid programs, certain statutory modifications could be made to decrease program abuses. In addition, while the Federal Government currently has many authorities to combat fraud and abuse in the Medicare and Medicaid programs, similar authorities to address abuses in private health plans do not exist. Therefore, we believe that it is appropriate to extend many statutes that currently only apply to the Medicare and Medicaid programs to all payers. These statutes include certain civil monetary penalty and exclusion provisions, and prohibitions on kickbacks and physician self-referral.

Question. Does the fiscal year 1995 budget adequately address your need to go after health care fraud? If you can save \$4 for each \$1 invested, isn't the President missing an opportunity to save money by not requesting a bigger IG budget?

Answer. In fiscal year 1990, our office returned \$61 for every dollar appropriated to us. The "savings" generated by our office are comprised of savings, fines, restitutions, judgements, settlements, recoveries, restitutions, and receivables. The vast majority of the savings generated by our office are in the form of savings or "funds put to better use." Based on our audit and inspection activity, we also make recommendations for the recovery of questioned and unsupported costs or charges to the programs managed by the Department. Finally, our investigative activities result in court-ordered fines, restitutions, judgments, as well as settlements and civil monetary penalties imposed by our office. Both the recovery of questioned costs and

our investigative activities result in about \$6 being recouped by the Government for every dollar spent on these activities.

Therefore, we believe that additional moneys given to our office would be a sound investment. One way to leverage our limited resources is to use a portion of recovered funds to increase fraud investigations.

We support the establishment of a health care fraud and abuse control account. Such an account would receive Federal moneys collected from health care fraud cases that would not otherwise be returned to the program that suffered the loss. Funds deposited in this account would include money recovered in health care fraud cases such as criminal fines, civil penalties and damages in cases brought under the False Claims Act (other than restitution or funds awarded to relators), administrative penalties and assessments (other than funds returned to original payers, such as the Medicare Trust Funds, CHAMPUS, the States), and certain amounts from forfeiture of property.

QUESTIONS SUBMITTED BY SENATOR SLADE GORTON

Question. Commissioner Chater, I was frankly appalled when Senator Cohen's Aging Committee Report was released earlier this year. I could not believe that the Social Security Administration is paying hundreds of millions of taxpayer dollars to drug addicts and alcoholics, who turn around and use the money to buy more drugs and alcohol! I was shocked that even when safeguards were in place to require treatment and a representative payee, the Social Security Administration was horribly lax in enforcement.

Are all the accusations in the report true? What has the SSA been doing with taxpayer's dollars all this time? And, although you went through some of it in your testimony, could you briefly summarize what SSA is doing to correct this egregious situation?

Answer. I am very concerned about the accusations in the report. Let me assure you that allegations of abuse are taken very seriously, and we have undertaken numerous efforts to ferret out abuse and improve the administration of our programs.

In collaboration with the Public Health Service's Substance Abuse and Mental Health Services Administration, we have taken major steps to improve referral and monitoring services for Supplemental Security Income [SSI] recipients disabled by drug addiction and alcoholism [DA&A]. We developed a new improved contract process structured to require each Referral and Monitoring Agency contractor to perform numerous specified tasks that will assure better service to SSI recipients and greater management oversight by SSA of the referral and monitoring process. These new contracts are currently in place in 34 States and the District of Columbia, and we plan to expand these new contracts into the remaining States by the end of this fiscal year.

We are also working to encourage non-profit organizations to serve as representative payees for SSI recipients who are disabled by DA&A. Finally, we are conducting demonstration projects to test alternatives for providing representative payees and for providing effective treatment and rehabilitation services for these individuals.

Question. I have asked thousands of constituents in my home State of Washington what they think on this subject. Overwhelmingly, they were disgusted by this flagrant waste of taxpayer funds. Let me just read a few comments I received back:

A man in Sequim, WA said this was "Shocking and ridiculous!" A woman in Oak Harbor urged that it be "stopped immediately," while a woman in Seattle told me how she was "appalled" by this story. A man from Lynwood says that it "must stop!" and a woman in Seattle tells me that she is "tired of hearing that this is [her] government" doing these things. And finally, a man from Kent states "It's time to stop this nonsense and be responsible and frugal with tax dollars." This is just a sampling of the outrage expressed to me by my constituents.

Commissioner Chater, do you understand why these people feel this way? Do you understand why they are so angry and mistrustful of government—when their tax dollars are being wasted like this?

Answer. I can certainly understand why your constituents feel this way. Although substance addiction is a disease which can legitimately be the basis for a finding of disability, the American public has a right to expect that those disabled by substance abuse addictions will not simply continue on the Supplemental Security Income [SSI] disability payment rolls without taking responsibility for themselves. Unlike many other disabled individuals, those suffering from substance abuse can, to varying degrees, influence their recovery by their own actions. The public has the right, therefore, to expect that they will seek recovery from their addiction and become self-supporting.

We take these concerns very seriously. And, as I have already indicated, we have been working hard to improve our administration of this area. We need to ensure that the public has confidence in the program and believes that it is managed well and is not fraught with abuse. On balance, though, we want to treat all individuals equitably and with compassion. I believe the administrative actions we have taken will help to balance these concerns.

Question. Your Agency recently paid out \$32 million in employee bonuses, while at the same time lobbying Congress for an additional \$200 million to speed up processing of a backlog of claims. Now the Aging Committee report points out that SSA has been spending hundreds of millions of dollars to help addicts and alcoholics feed their addiction. On top of all this, seniors have been told they have to pay more taxes on some of their Social Security benefits.

Now that we're taking away more of our seniors' money through higher taxes, what do you suggest I tell them about the bonuses, the fraud and abuse in the SSI and DI programs, and the huge backlog of claims sitting over at the Social Security Administration? How do I tell them that higher taxes on their benefits are fair?

Answer. You have raised a number of important issues which I shall address in turn.

EMPLOYEE BONUSES

The Civil Service Reform Act [CSRA] authorizes cash performance awards to be paid to employees who perform exceptionally well. The purpose of this provision is to reward the best workers in the Federal government. Last year, Social Security Administration [SSA] employees nationwide received performance awards totalling \$32 million, an amount which represents 1.15 percent of the overall SSA payroll of \$2.8 billion. This percentage is comparable to that of other executive branch agencies.

It is important to note that none of the performance awards came out of the \$200 million set aside by Congress to help reduce the backlog of disability cases. When evaluating the performance awards paid to SSA employees, one must also consider that our workforce has dropped by almost one-fourth (from 84,000 to 64,000) since 1983, while workloads have grown considerably. I believe that SSA employees have a right to be proud of the work they do, and the CSRA performance awards were created to encourage and reward talent, effort, and productivity.

PAYMENTS TO DRUG ADDICTS AND ALCOHOLICS

Over the years it has become clear to the medical profession that substance addiction is a disease which can legitimately be the basis for a finding of disability. The Congress and the Administration concur with this finding. However, I agree with you that the American public has a right to expect that those disabled by substance addictions will not simply continue on Supplemental Security Income [SSI] disability payment rolls without taking responsibility for themselves. Unlike many other disabled individuals, those suffering from substance abuse can, to varying degrees, influence their recovery by their own actions. The public has the right, therefore, to expect that they will do all they can to cooperate in recovering from their addiction and become self-supporting.

In addition to meeting the medical eligibility requirements, Congress included two special requirements in the law for SSI recipients who are disabled due to drug addiction and alcoholism [DA&A]. Congress required that: these individuals undergo appropriate treatment for their addiction at approved facilities when treatment is available, and demonstrate compliance with the terms and conditions of such treatment. Also, they must receive their SSI payments through a representative payee.

These two special requirements were intended to prevent individuals from receiving cash payments without being involved or while being only marginally involved in available treatment programs, and to prevent them from using cash payments to purchase drugs or alcohol.

ADMINISTRATION OF THE SPECIAL PROVISION CONCERNING TREATMENT REFERRAL AND MONITORING

SSA's role in administering this provision is not to determine what kind of treatment is appropriate, but rather to find qualified agencies which are capable of making that determination. Nevertheless, we have evaluated how SSA administered this provision in the past and realize that we need to make improvements.

Until recently, SSA has attempted to ensure compliance with the treatment and monitoring requirements through agreements with States and private contractors serving as Referral and Monitoring Agencies [RMA's]. In past years, however, SSA

found it difficult to establish agreements with RMA's covering all geographical locations in a uniform manner because of small workloads in some States and lack of funding to cover the whole country. As of October 1993, we had RMA's in only 18 States and only 45 percent of the persons identified as receiving SSI based on DA&A were being monitored. In addition, we did not provide specific guidance to the RMA's as to how they should function on a day-to-day basis.

As I previously reported, however, based on our collaboration with the Public Health Service's Substance Abuse and Mental Health Services Administration [SAMHSA], we have taken major steps to improve referral and monitoring services. We have developed a contract process structured to require each RMA contractor to perform numerous specified tasks that will assure both better service to SSI recipients and greater management oversight by SSA of the referral and monitoring process. These new contracts are now in place in 34 States and the District of Columbia and will be in place in the remaining States by the end of this fiscal year.

SSI'S REPRESENTATIVE PAYEE REQUIREMENT FOR RECIPIENTS DISABLED BY DA&A

Paying benefits to a responsible third party has long been seen as a way of meeting the recipient's basic needs, without supporting his addiction. Representative payees are instructed to use benefits to provide for the recipient's basic needs, such as food, shelter, clothing and medical care.

We believe that most payees are conscientious in trying to meet these obligations. However, this can be a difficult task in the case of some substance abusers. Since these individuals know the amount of their monthly payments, they sometimes manipulate or intimidate their representative payees into giving them cash. We believe that one answer to this problem is to encourage non-profit organizations and treatment centers to serve as representative payees. Organizational payees can create a closer link between benefit payments and treatment efforts and would be less likely to yield to beneficiary pressures for cash. We have for some time been working with community service groups to provide volunteer representative payees for beneficiaries who need them. However, it is often difficult to find volunteers willing to serve as payees for substance abusers. In an effort to meet this need, we have begun a systematic recruitment effort aimed at professionals who serve substance abusers. We also are taking part in demonstration projects with SAMHSA which involve representative payee selection.

BACKLOG OF DISABILITY CLAIMS

SSA continues to face the problem of increasing disability applications, resulting in workload backlogs. In fiscal year 1995, an estimated 2.9 million initial disability claims will be forwarded to the State Disability Determination Services for processing. This represents a 69 percent increase over the number of claims as recently as fiscal year 1990. As applications move through the initial decision phase and into the appeals process, the Office of Hearings and Appeals [OHA] is also experiencing an unprecedented growth in hearing workloads. By fiscal year 1995, these workloads will grow by 232,000 hearings over fiscal year 1990 receipt levels, an increase of 75 percent.

We have targeted these growing disability caseloads as a key investment area that requires both a long- and short-term strategy with several interrelated parts. We believe that the long-term key to handling the problem is to reengineer current processes and procedures, and are strongly committed to implementing innovative, cost-effective alternatives to improve service. In the short-term, however, we will combine additional resources with short-term management actions to focus on containing the problem. We have been reallocating resources into disability workload processing for some time. The workyear effort devoted to the Disability Insurance and SSI programs has increased from 50 percent of SSA's overall workyear total in fiscal year 1983 to 58 percent in fiscal year 1993. Disability program growth continues to be a dynamic problem that we are studying carefully so we can better project current and future needs.

FAIRNESS OF TAXATION OF BENEFITS

Finally, I will attempt to respond to your question regarding the fairness of the recent tax increase on Social Security benefits. Supporters of the tax increase would argue that it promotes tax equity by treating Social Security benefits more like private pensions and civil service benefits. Further, revenues from the increased taxation are earmarked for the Hospital Insurance Trust Fund to help pay for Medicare services utilized by Social Security beneficiaries.

Question. I want to commend you for the initiatives you have started to clean up this mess. And I want to commend the hard work of Senator Cohen, who brought this situation to our attention and who successfully offered an amendment, which went on to pass the Senate, to correct this injustice.

What can I do as a Senator to help clean up the wide-spread abuses within your agency immediately? When can I go back to my constituents and tell them, with a straight face, that these types of flagrant abuses will never occur again?

Answer. I share your concern and appreciate your offer to help. As you know, the Social Security Administration [SSA] has been faced with unprecedented disability workloads which have strained already scarce resources. Even so, in most instances, SSA employees do exemplary work and take their responsibilities seriously. This includes promptly addressing allegations of program abuse.

We have undertaken numerous efforts over the past year to ferret out abuse and improve administration of our programs. Our administrative initiatives will help us to maintain the integrity of the SSI disability program and achieve a higher level of public confidence in the program. Nevertheless, we are continuing to work to identify and evaluate the full range of remedies available in order to fully address this problem. We also support deficit-neutral legislation which we think would help to strengthen the program, including some of the measures that were recently passed by the House and Senate.

We look forward to continuing our cooperative efforts to address this difficult and serious problem, and we will be happy to work with you to consider other approaches that will help us to eliminate instances of abuse in the SSI program.

CONCLUSION OF HEARINGS

Senator HARKIN. Thank you very much for being here. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 12:18 p.m., Friday, May 13, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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